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PROSPECTUS

Palvella Therapeutics, Inc.

Up to 5,634,504 Shares of Common Stock

This prospectus relates to the proposed offer and resale or other disposition from time to time by the selling stockholders identified in this prospectus of up to (i) 3,168,048 shares of our common stock, par value $0.001 per share, and (ii) 2,466,456 shares of our common stock underlying pre-funded warrants (the "Pre-Funded Warrants") held by certain of the selling stockholders. The shares of common stock registered by this prospectus are collectively referred to herein as the "Resale Shares."

We are registering the resale of the Resale Shares pursuant to a registration rights agreement (the "Registration Rights Agreement") between us and the selling stockholders. Our registration of the resale of the Resale Shares does not mean that the selling stockholders will offer or sell all or any of the Resale Shares. The selling stockholders may offer, sell or distribute all or a portion of their Resale Shares from time to time directly or indirectly through one or more underwriters, broker-dealers or agents, and in one or more public or private transactions, which may involve crosses or block transactions. The Resale Shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale or at negotiated prices. See the section entitled "*Plan of Distribution*" for more information.

We will not receive any proceeds from any sale of the Resale Shares by the selling stockholders pursuant to this prospectus. Upon any exercise of the Pre-Funded Warrants by payment of cash, however, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. We have agreed to bear the expenses in connection with the registration of the resale of the Resale Shares to be offered by this prospectus by the selling stockholders except for any underwriting discounts and commissions or transfer taxes relating to the sale of the Resale Shares, which will be borne by the selling stockholders.

Our common stock is listed on the Nasdaq Capital Market under the symbol "PVLA." On January 10, 2025, the closing price for our common stock was $13.97 per share.

See the section entitled "Risk Factors" beginning on page 9 of this prospectus to read about factors you should consider before buying 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 January 16, 2025.

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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference to exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement or amendment. Neither we nor the selling stockholders have authorized anyone to provide you with different information. Neither we nor the selling stockholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.

EXPLANATORY NOTE

On December 13, 2024 (the "Closing Date"), Palvella Therapeutics, Inc., a Nevada corporation (the "Company" or "Palvella") (previously named Pieris Pharmaceuticals, Inc. and our predecessor company ("Pieris")), consummated the previously announced merger pursuant to the terms of that certain Agreement and Plan of Merger, dated as of July 23, 2024 (the "Merger Agreement"), by and among the Company, Polo Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Pieris (the "Merger Sub"), and Palvella Therapeutics, Inc., a Delaware corporation ("Legacy Palvella").

Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Palvella, with Legacy Palvella 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 Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc.

In accordance with the terms and subject to the conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger, each outstanding share of Legacy Palvella capital stock (including shares of Legacy Palvella common stock and Legacy Palvella preferred stock) (excluding dissenting shares) was converted into the right to receive a number of shares of Palvella common stock, and (ii) at the effective time of the Merger, the Company issued an aggregate of approximately 6,787,415 shares of its common stock to Legacy Palvella stockholders, based on an exchange ratio of 0.309469242 shares of the Company's common stock for each share of Legacy Palvella capital stock outstanding immediately prior to the Merger, but excluding shares to be canceled pursuant to the Merger Agreement, resulting in approximately 8,316,929 shares of the Company's common stock being issued and outstanding immediately following the effective time of the Merger.

Concurrently with the execution of the Merger Agreement on July 23, 2024, Pieris entered into a securities purchase agreement (the "Purchase Agreement") with the selling stockholders identified in this prospectus, pursuant to which, among other things, on the Closing Date and immediately following the consummation of the Merger, the selling stockholders purchased (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Legacy Palvella), and the Company issued and sold to the selling stockholders, an aggregate of 3,168,048 shares of the Company's common stock at a price per share equal to $13.9965 (the "Purchase Price"), and/or in lieu of the Company's common stock to certain purchasers who so choose due to beneficial ownership concerns, pre-funded warrants (the "Pre-Funded Warrants") to purchase 2,466,456 shares of the Company's common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price minus $0.001 (the "PIPE Financing"). The gross proceeds from the PIPE Financing were approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest payable under the outstanding convertible notes issued by Legacy Palvella, before paying estimated expenses. The closing of the PIPE Financing occurred on December 13, 2024, immediately following the consummation of the Merger.

On December 13, 2024, the Company and the selling stockholders identified in this prospectus entered into a registration rights agreement (the "Registration Rights Agreement") pursuant to which the such selling stockholders are entitled to certain resale registration rights with respect to shares of the Company's common stock issued to the selling stockholders and any shares of the Company's common stock issuable upon exercise of the Pre-Funded Warrants. Pursuant to the Registration Rights Agreement, the Company is required to prepare and file a resale registration statement with the Securities and Exchange Commission ("SEC") within 30 days following the closing of the PIPE Financing. The Company is obligated to use commercially reasonable efforts to cause this registration statement to be declared effective by the SEC within 90 days following the closing of the PIPE Financing (or within 120 days following the closing of the PIPE Financing if the SEC reviews the registration statement). The registration statement of which this prospectus is a part relates to the resale of the shares of common stock issued in the PIPE Financing and the shares of common stock issuable upon exercise of the Pre-Funded Warrants issued in the PIPE Financing.

As of the open of trading on December 16, 2024, the common stock of the Company began trading on the Nasdaq Capital Market under the symbol "PVLA."

ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption "*Selling Stockholders*," from time to time, of up to an aggregate of 5,634,504 shares of common stock, which includes 2,466,456 shares of common stock issuable upon the exercise of the Pre-Funded Warrants. We are not selling any of the Resale Shares under this prospectus, and we will not receive any proceeds from the sale of the Resale Shares offered hereby by the selling stockholders. Upon any exercise of the Pre-Funded Warrants by payment of cash, however, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants

Neither we, nor the selling stockholders, have authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which it relates, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered, or shares are sold on a later date. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus incorporates by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included or incorporated by reference in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" contained in this prospectus, and under similar headings in other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

A prospectus supplement may add to, update, or change the information contained in this prospectus. You should read both this prospectus and any applicable prospectus supplement together with additional information described below under the heading "*Where You Can Find Additional Information*" or incorporated by reference herein.

Unless the context otherwise indicates, references in this prospectus to "Company," "we," "our" and "us" refer, collectively to Palvella Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiaries (including Palvella Therapeutics, a Delaware corporation ("Legacy Palvella")).

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains and/or incorporates by reference statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the strategies, prospects, plans, expectations and objectives of management of our future operations;
- the expected benefits of and potential value created by the Merger (as defined herein) for the stockholders of the Company;
- the potential of, and expectations regarding, our programs, including QTORIN™ rapamycin, and its research-stage opportunities, including its expected therapeutic potential and market opportunity
- the expected timing of initiating, as well as the design of, our Phase 2 clinical trial of QTORIN™ rapamycin in cutaneous vascular malformation
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the ability to protect and enhance our products and intellectual property, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- developments and projections relating to our competitors or industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- expectations concerning our relationships and actions with third parties, including any license and collaborations with such third parties;
- future regulatory, judicial and legislative changes in our industry in the United States, Europe, and other jurisdictions;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- our ability to utilize our proprietary drug discovery platform to develop a pipeline of product candidates to address unmet needs in rare skin disease indications;
- the outcome of clinical trials of our product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements;
- the timing of availability of data from our clinical trials;
- our plans to research, develop and commercialize our current and future product candidates;
- our ability to protect our intellectual property and proprietary technologies;
- our reliance on third parties, contract manufacturers, and contract research organizations;
- our ability to develop and advance current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases we are targeting;
- expectations regarding potential for accelerated approval or other expedited regulatory designation;
- our competitive position and the success of competing therapies that are or may become available;
- estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates; and

- our ability to obtain and maintain regulatory approval of our product candidates and our expectations regarding particular lines of therapy.

These forward-looking statements are based on information available to us at the time of this prospectus or the documents incorporated by reference herein and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties, and other factors. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements, including those set forth in this prospectus in the section entitled "Risk Factors" and in our periodic filings with the Securities and Exchange Commission (the "SEC"). Our SEC filings are available publicly on the SEC's website at www.sec.gov. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in any accompanying prospectus supplement. Should one or more of the risks or uncertainties described in this prospectus, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements.

You should read this prospectus and any accompanying prospectus supplement if any, completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this prospectus. We qualify all of our forward-looking statements by these cautionary statements.

PROSPECTUS SUMMARY

Our Company

We are a clinical-stage biopharmaceutical company whose vision is to become the leading rare disease biopharmaceutical company focused on developing and, if approved, commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases, for which there are no FDA approved therapies. We intend to leverage our versatile QTORIN™ platform to treat these patients. The QTORIN platform is designed to generate new therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of rare, genetic skin diseases. Our lead product candidate, QTORIN 3.9% rapamycin anhydrous topical gel, or "QTORIN rapamycin", is in clinical development for two of these diseases: microcystic lymphatic malformations, or "microcystic LM", and cutaneous venous malformations. QTORIN rapamycin contains the active pharmaceutical ingredient rapamycin, also known as sirolimus, which is an inhibitor of mammalian target of rapamycin, or "mTOR", a kinase that plays a key role in cell growth and proliferation. The QTORIN platform is novel and has only generated one program to date, QTORIN rapamycin, and clinical evidence to support this candidate is preliminary and limited at this time.

We currently have one ongoing clinical trial and one clinical trial planned to start in the fourth quarter of 2024, both of which are currently or will be conducted in the United States. Our ongoing trial, SELVA, is a Phase 3 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin in the Treatment of Microcystic LM. We previously announced topline Phase 2 clinical trial results from the multi-center, open-label study of 12 subjects receiving QTORIN™ rapamycin once-daily for 12-weeks. The Phase 2 clinical trial featured multiple pre-specified efficacy assessments, including clinician and patient global impression assessments as well as assessments of individual clinical manifestations that are important disease burdens for individuals living with microcystic LMs. All participants in the Phase 2 clinical trial demonstrated improvements on the Clinician Global Impression of Change scale, with all participants in the study rated as either "Much Improved" (n=7, 58%) or "Very Much Improved" (n=5, 42%) after 12-weeks of treatment compared to the pre-treatment baseline period. We expect to report top-line data for the Phase 3 study in approximately 40 participants with microcystic LM in the first quarter of 2026.

A baseline-controlled study is a clinical study in which the patient's condition during treatment is compared with their condition before treatment. In such studies, participants serve as their own control. In a placebo-controlled study, patients are randomized prior to treatment to receive either study drug or matching placebo and to determine how the efficacy of the treatment compares to placebo. Baseline-controlled studies are appropriate when the effects are dramatic, occur rapidly following treatment, and are unlikely to have occurred spontaneously (e.g., general anesthesia, cardioversion, measurable tumor shrinkage).

Microcystic LM is a serious, chronically debilitating, and lifelong disease of the lymphatic system characterized by lymphorrhea and acute cellulitis. It is estimated that there are more than 30,000 diagnosed patients in the United States with microcystic LM. The specific pathophysiology of microcystic LM is the result of somatic activating mutations in primarily Phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha, or "PIK3CA" which result in increased activation of the PI3K/mTOR pathway and subsequent lymphatic hyperplasia.

We have received Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation from the FDA for QTORIN rapamycin for the treatment of microcystic LM. We have also received Fast Track Designation from the FDA for the treatment of venous malformations.

There are no FDA-approved therapies currently indicated for either microcystic LM or cutaneous venous malformations. If approved for the treatment of microcystic LM or cutaneous venous malformations, we believe QTORIN rapamycin has the potential to become the standard of care for these diseases.

We also have a planned study for cutaneous venous malformations, a Phase 2 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin for the Treatment of Cutaneous Venous Malformations expected to start in the fourth quarter of 2024. Cutaneous venous malformations are a serious disease with a high unmet need characterized by dysregulated growth of malformed veins impacting the skin, causing functional impairment and deformity. It is estimated that there are more than 75,000 patients in the United States with cutaneous venous malformations. This Phase 2 baseline-controlled clinical trial is expected to be in approximately 15 participants in this patient population and we expect to report top-line data in the fourth quarter of 2025. The trial is covered by the same Investigational New Drug Application, or "IND," submitted to the FDA by us for QTORIN rapamycin.

We also have additional preclinical research programs based on our QTORIN platform for the treatment of serious, rare genetic skin diseases for which we believe there are significant unmet needs. As we plan to expand our pipeline into new rare skin diseases, we plan to generate new product candidates with our QTORIN platform. Despite our intentions with respect to our QTORIN platform, our business carries substantial risks. The QTORIN platform is novel and has only generated one program to date, QTORIN rapamycin, and clinical evidence to support this candidate is preliminary and limited at this time.

We currently plan to pursue marketing approval for QTORIN rapamycin for several indications in the U.S. through a Section 505(b)(2) NDA and will be relying on the listed drug, RAPAMUNE, a previously approved drug for organ rejection prophylactic. A Section 505(b)(2) NDA enables the applicant in certain circumstances to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the listed product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. There can be no assurance that the FDA will agree with our use of the Section 505(b)(2) NDA pathway to seek approval for our product candidates in various indications.

Additionally, a number of factors could delay or prevent regulatory approval for our product candidates, including, but not limited to, the need to conduct additional trials, the acceptability of the clinical evidence presented to regulatory agencies such as the baseline-controlled Phase 3 study, issues with our QTORIN platform which has not yet been approved in any product, and the efficacy endpoints utilized in the clinical studies. See the sections entitled "*Our Business*" and "*Risk Factors—Risks Related to the Discovery, Development, Regulatory Approval and Commercialization of Our Product Candidates*" in this prospectus for more information.

As a novel platform, our QTORIN platform may never result in a product candidate that receives regulatory approval. Negative results in the development of QTORIN rapamycin for either the treatment of microcystic LM or cutaneous venous malformations may also impact our ability to obtain regulatory approval for other product candidates which we expect to develop based on our QTORIN platform. Our Phase 2b clinical trial of QTORIN rapamycin in patients with Gorlin Syndrome and Phase 3 clinical trials of QTORIN rapamycin in patients with pachyonychia congenita failed to meet their respective primary endpoints. Past and any future failures in any one QTORIN-based program may decrease trust in our technology and may affect our ability to conduct clinical programs for other QTORIN-based product candidates. See the section entitled "*Risk Factors—Risks Related to the Discovery, Development, Regulatory Approval and Commercialization of Our Product Candidates*" in this prospectus for more information.

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*," following this prospectus summary. These risks include the following, among others:

- we have historically incurred significant operating losses and anticipates that it will continue to incur significant operating losses for at least the next several years. We may never achieve or maintain profitability;
- we have never generated revenue from product sales and may never achieve or maintain profitability;
- our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern;
- we will likely require substantial additional funding to finance its operations, which may cause dilution to our stockholders, and a failure to obtain this necessary funding when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations;
- our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of QTORIN rapamycin, which is in later stages of development than our other product candidates;

- we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would adversely impact our potential to generate revenue, our business and our results of operations;
- the rare genetic skin diseases we are currently targeting have no FDA-approved therapies, which subjects the design and execution of our clinical development program to complexities and known and unknown risks, including those related to novel and/or subjective clinical endpoints and varying patient population characteristics;
- our lead product candidates are based on our QTORIN platform and it is highly dependent on the successful development of this novel and unproven technology.
- we may be unable to obtain Orphan Drug Designation for certain of our product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved;
- our development and commercialization strategy for our product candidates depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of rapamycin. If we are not able to pursue this strategy, we may be delayed in receiving regulatory authority approval;
- Fast Track Designation granted for QTORIN rapamycin for the treatment of microcystic LM and, if granted, for any of our other product candidates by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval;
- even if QTORIN rapamycin or any future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success;
- we currently rely on contract manufacturer organizations, or "CMOs," to manufacture preclinical and clinical supplies of our product candidates and will rely on CMOs for the commercial supplies of any approved product candidate. The loss of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect its business; and
- we may not be able to obtain, maintain or enforce patent rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against it.

Private Placement of Common Stock and Pre-Funded Warrants

Concurrently with the execution of the Merger Agreement on July 23, 2024, Pieris entered into a securities purchase agreement (the "Purchase Agreement") with the selling stockholders identified in this prospectus, pursuant to which, among other things, on the Closing Date and immediately following the consummation of the Merger, the selling stockholders purchased (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Legacy Palvella), and the Company issued and sold to the selling stockholders, an aggregate of 3,168,048 shares of the Company's common stock at a price per share equal to $13.9965 (the "Purchase Price"), and/or in lieu of the Company's common stock to certain purchasers who so choose due to beneficial ownership concerns, the Pre-Funded Warrants to purchase 2,466,456 shares of the Company's common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price minus $0.001 (the "PIPE Financing"). The gross proceeds from the PIPE Financing were approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest payable under the outstanding convertible notes issued by Legacy Palvella, before paying estimated expenses. The closing of the PIPE Financing occurred on December 13, 2024, immediately following the consummation of the Merger.

In connection with the PIPE Financing, we granted certain registration rights with respect to the Resale Shares pursuant to the Registration Rights Agreement. As required by the Registration Rights Agreement, we agreed to, among other things, (i) file a registration statement under the Securities Act with the SEC to cover the resale of the Resale Shares by the selling stockholders within 30 days following the closing of the PIPE Financing, and (ii) use commercially reasonable efforts to cause this registration statement to be declared effective by the SEC within 90 days following the closing of the PIPE Financing (or within 120 days following the closing of the PIPE Financing if the SEC reviews the registration statement). The registration statement of which this prospectus is a part relates to the resale of the Resale Shares.

Corporate Information

On December 13, 2024, we completed a reverse merger transaction (the "Merger") with Legacy Palvella, and, upon completion of the Merger, we changed our name to "Palvella Therapeutics, Inc." Shares of our common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "PVLA" as of market open on December 16, 2024. Our principal executive office is located at 125 Strafford Avenue, Suite 360, Wayne, Pennsylvania 19087, and our telephone number is (484) 253-1461. Our website address is www.palvellatx.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You may obtain any of the documents filed by us with the SEC at no cost from the SEC's website at *http://www.sec.gov*.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

The Offering

Issuer	Palvella Therapeutics, Inc.
Shares of Common Stock Offered by the Selling Stockholders	Up to an aggregate of 5,634,504 shares of common stock, which includes 2,466,456 shares of common stock issuable upon the exercise of the Pre-Funded Warrants held by certain of the selling stockholders.
Shares of Common Stock Outstanding After this Offering	13,687,763 shares of common stock
Use of Proceeds	All of the Resale Shares offered by the selling stockholders pursuant to this prospectus will be sold by the selling stockholders for their respective accounts. We will not receive any proceeds from the sale of the Resale Shares covered by this prospectus. Upon any exercise of the Pre-Funded Warrants by payment of cash, however, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. See the section titled "*Use of Proceeds*."
Offering Price	The selling stockholders will offer the Resale Shares offered by this prospectus at the prevailing market prices or at privately negotiated prices.
Risk Factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Capital Market Symbol	PVLA

For additional information concerning the offering, see "*Plan of Distribution*" beginning on page 181.

The number of shares of common stock to be outstanding after this offering is based on 11,221,307 shares of our common stock outstanding as of December 20, 2024, assumes the full exercise of the Pre-Funded Warrants, and excludes:

- 1,789,131 shares of common stock issuable upon the vesting and exercise of outstanding stock options; and
- 1,551,508 shares of our common stock reserved for future issuance under our 2024 Equity Incentive Plan (the "2024 Plan").

RISK FACTORS

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto, and the other financial information concerning us included elsewhere in this prospectus. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have historically incurred significant operating losses and anticipate that we will continue to incur significant operating losses for at least the next several years. We may never achieve or maintain profitability.

We have historically incurred significant operating losses and have never generated any revenue. Our operating loss for the years ended December 31, 2023 and 2022 was $11.9 million and $18.0 million, respectively, and for the nine months ended September 30, 2024 was $13.5 million. As of September 30, 2024, we had an accumulated deficit of $89.8 million. We expect to continue to incur significant operating losses for at least the next several years, and we may never achieve or sustain profitability. We have historically devoted substantially all of our efforts to identifying, researching and conducting preclinical and clinical activities for our product candidates, developing our QTORIN platform, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. We have never obtained regulatory approval for, or commercialized, any products. We anticipate that our expenses will increase substantially for the foreseeable future if, and as, we:

- seek regulatory approval for QTORIN rapamycin for the treatment of microcystic LM and any other product candidates that successfully complete clinical trials;
- continue clinical development of our product candidates, including our ongoing Phase 3 clinical trial for QTORIN rapamycin in patients with microcystic LM, and our planned Phase 2 clinical trial for QTORIN rapamycin in patients with cutaneous venous malformations;
- continue preclinical development of our product candidates, including QTORIN rapamycin for other mTOR-driven skin diseases;
- establish a specialized commercial organization in the United States to commercialize any product candidate for which we obtain marketing approval;
- initiate and continues relationships with suppliers and manufacturers and has commercial quantities of our product candidates manufactured at acceptable cost and quality levels and in compliance with the FDA and other regulatory requirements;
- initiate additional clinical trials and preclinical studies for our other product candidates;
- seek to identify and develop or in-license additional product candidates;
- incur additional costs associated with operating as a public company, which will require us to add operational, financial, and management information systems and personnel, including personnel to support product development, any future commercialization efforts, and our transition to a public company;
- expand our infrastructure and facilities to accommodate our growing employee base, including adding equipment and physical infrastructure to support our research and development; and
- maintain, expand and protect our intellectual property portfolio.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining regulatory approval, procuring commercial-scale manufacturing, and marketing and selling any products for which it obtains regulatory approval. We have never obtained regulatory approval, procured commercial-scale manufacturing or marketed any product, and we may never succeed in these activities. Even if we do obtain regulatory approval for and begin commercializing QTORIN rapamycin for microcystic LM, cutaneous venous malformations, or any other indication or any future product candidates, our ability to become profitable will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for any such product candidate and the degree of market acceptance we achieve.

Even if we do 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 would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of our investment.

Our limited operating history may make it difficult to evaluate our business to date and our future viability.

We are a late clinical stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and has not generated any revenue from product sales. As an organization, We have limited experience successfully completing pivotal clinical trials, and has not yet demonstrated an ability to obtain marketing approval, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have little or no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as it could be if it had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our product candidates. Even if we receive regulatory approval for any product candidate, it does not know when or if such product candidate will generate product revenue. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology and product candidates. In the future, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may also need to secure strategic collaborations with partners in order to commercialize any approved product candidates outside of the U.S. market. We may not be successful in making such a transition or in securing such strategic collaborations.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern. In our financial statements for the year ended December 31, 2023, we concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in our report on our financial statements for the year ended December 31, 2023 with respect to this uncertainty. Our ability to continue as a going concern will require it to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, it would be forced to delay, limit, reduce or terminate our product development or future commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. In future required quarterly assessments, we may again conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to it on commercially reasonable terms, if at all. Based on our current business plans, we believe that the anticipated cash and cash equivalents after the merger will be sufficient for it to fund our operating expenses and capital expenditure requirements through at least the next 33 months. This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect.

We will likely require substantial additional funding to finance our operations, which may cause dilution to our stockholders, and a failure to obtain this necessary funding when needed on acceptable terms, or at all, could force it to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

As of September 30, 2024, we had cash and cash equivalents of $14.2 million. Based upon our current operating plan, we believe that our cash and cash equivalents, together with the proceeds from the PIPE Financing, will be sufficient to fund our planned operations through in to the second half of 2027. We have based this estimate on assumptions that may prove to be wrong, and it could exhaust our available capital resources sooner than it expects. To finance our operations beyond that point we may need to raise additional capital, which cannot be assured. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. To the extent that we raise additional capital by issuing equity securities, our existing stockholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of a common stockholder. Any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to it. We may seek additional capital due to favorable market conditions or strategic considerations even if it believes We have sufficient funds for our current or future operating plans. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if it believes We have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including, but not limited to:

- the scope, progress, timing, results and costs of researching and developing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the number and scope of clinical programs it decides to pursue;
- the cost, timing and outcome of seeking regulatory approvals of our product candidates; the cost of manufacturing our product candidates and any products it commercializes, including costs associated with building out our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing, receipt and amount of sales of any future approved products, if any;
- the timing and amount of milestone or royalty payments due to Ligand, under Ligand Agreements (as defined below), or under similar arrangements with any future collaboration or licensing partners;
- the expenses needed to attract and retain skilled personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio.

Adequate additional funds may not be available when we need them, on terms that are acceptable to it, or at all. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to reduce our workforce, delay, limit, reduce or terminate our research and development activities, preclinical studies, clinical trials or other development activities and future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourself. In addition, attempting to secure additional financing may divert the time and attention of our management from daily activities and distract from our research and development efforts.

Our development funding agreement with Ligand obligates it to make certain milestone payments, some of which will be triggered prior to our commercialization of any of our product candidates.

Certain of the milestone payments payable by us in connection with the Ligand Agreements are due upon events that will occur prior to our planned commercialization of our lead product candidate, QTORIN rapamycin. Accordingly, we may be required to make payments in an aggregate amount of up to $5.0 million prior to the time at which it is able to generate revenue, if any, from sales of QTORIN rapamycin for any indication, if approved. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to it, or at all. In order to make the required payments when due, we may be required to divert our capital resources by delaying, limiting, reducing or terminating our product development or future commercialization efforts, or we may have to grant rights to develop and market product candidates that it would otherwise develop and market ourself. If we are required to raise funds but is unable to do so, or if it is unable to otherwise maintain sufficient liquidity to make our payment obligations if and when they become due, we may be in material breach of the Ligand Agreements, and Ligand may seek legal action or remedies against us (including by seeking to terminate the Ligand Agreements), which would harm our business, financial condition, results of operations and prospects. If we are able to raise funds, we may not be able to do so on terms that are favorable to it, and our existing stockholders may experience substantial dilution, we may agree to certain covenants limiting or restricting our ability to take specific actions, or we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates.

Our ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

Our federal NOL carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Our federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of such federal NOL carryforwards is limited to 80% of our current year taxable income. It is uncertain if and to what extent limitations under state law may differ. As of December 31, 2023, we had federal NOL carryforwards of approximately $36.7 million, which are available to reduce future federal taxable purposes and have an indefinite carryforward. We have NOLs for state income tax purposes of $37.6 million, which are available to reduce future state taxable income through 2038.

In addition, as noted above, under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a cumulative change in the corporation’s ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use our pre-change NOL carryforwards and certain other pre-change tax attributes to offset our post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of the Merger and the PIPE Financing or subsequent shifts in our stock ownership. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. Because our ability to utilize our NOL carryforwards and certain other tax attributes could be limited as described above, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

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

Clinical drug development is a lengthy, complex and expensive process, with an uncertain outcome. we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidates.

Our lead product candidate, QTORIN rapamycin, is in clinical development and the risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. Clinical trial failure may result from a multitude of factors including flaws in trial design, carryover effect, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy, and failure in clinical trials can occur at any stage. For example, our Phase 2b clinical trial of QTORIN rapamycin in patients with Gorlin Syndrome and Phase 3 clinical trials of QTORIN rapamycin in patients with pachyonychia congenita failed to meet their respective primary endpoints.

We are currently conducting our Phase 3 clinical trial of QTORIN rapamycin for the treatment of microcystic LM, for which it expects to report top-line data in the first quarter of 2026. We are also planning to conduct a Phase 2 clinical trial of QTORIN rapamycin for the treatment of cutaneous venous malformations, for which it expects to report top-line data in the fourth quarter of 2025. Our other programs under evaluation for the treatment of other serious, rare genetic skin diseases and other genetic diseases are in early-stage preclinical development.

We may experience numerous unforeseen events that could delay or prevent our ability to receive marketing approval for our product candidates, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may halt or suspend an ongoing trial;
- clinical trials of our product candidates may fail to show safety, efficacy or an acceptable benefit-risk profile, produce negative or inconclusive results, and we may decide, or regulators may require it, to conduct additional nonclinical studies or clinical trials or abandon drug development programs;
- the design of any of our clinical trials may be flawed, and those flaws may not become apparent until such clinical trial is well advanced or completed;
- regulators may not agree with our selection of novel endpoints or other key clinical trial design features, such as choice of control, used in our clinical evaluation of our rare disease product candidates; for example, the FDA has commented that a placebo-controlled trial or additional trials assessing different clinical endpoints may be required to assess the efficacy of QTORIN rapamycin for the treatment of microcystic LM;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the number of subjects required for clinical trials of our product candidate may be larger than anticipated, enrollment in the clinical trials for our product candidates may be slower than we anticipate, we may be difficult to identify and enroll suitable participants given the small patient populations of the diseases it is targeting, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than it anticipates;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites and CROs; the cost of clinical trials of our product candidates may be greater than we anticipate, particularly if the FDA or other equivalent foreign regulatory authorities require post-marketing studies and/or a patient registry; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that currently contemplated, if it is unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining regulatory approval, if it receives such approval at all, receive more limited or restrictive regulatory approval, be subject to additional post-marketing testing requirements. If we experience any delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates may not be successful. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development process and jeopardize our ability to receive regulatory approval and commence product sales and generate revenues. Any of these occurrences could materially adversely affect our business, financial condition, results of operations and prospects.

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of QTORIN rapamycin, which is in later stages of development than our other product candidates.

We currently have no products that are approved for commercial sale. We are developing our lead product candidate, QTORIN rapamycin, for the treatment of two rare genetic skin diseases. We are currently evaluating QTORIN rapamycin in patients with microcystic LM in our Phase 3 clinical trial. We are also developing QTORIN rapamycin for patients with cutaneous venous malformations. Additionally, we are developing other research-stage product candidates, but these product candidates are in earlier stages of development. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the continued clinical evaluation of QTORIN rapamycin and the commercialization of this product candidate for the treatment of microcystic LM, following regulatory approval, if received. Accordingly, the success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of QTORIN rapamycin.

The clinical and commercial success of QTORIN rapamycin and any future product candidates will depend on many factors, including the following:

- the ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and may depend substantially upon the performance of certain third-party contractors;
- the ability to demonstrate the safety, efficacy and acceptable benefit-risk profile of our product candidates to the satisfaction of the FDA and equivalent foreign regulatory authorities;
- delays in developing and testing, or inability to develop and test, any clinical outcome assessments to the extent necessary for the FDA and equivalent foreign regulatory authorities to agree to their use as endpoints utilized in a clinical trial to support labeling claims;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any, or experienced by competitors who are developing topical rapamycin (also known as sirolimus) products or who are targeting the same indications in the rare genetic skin diseases space;
- the timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities and, if granted, completion of any required post-marketing studies or trials and available funding to perform any such studies or trials;
- the ability of any CMO, upon which we rely to manufacture clinical and commercial supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or "cGMP";
- our ability to successfully develop a targeted rare disease commercial strategy and thereafter establish sales, marketing and distribution capabilities to launch and commercialize our product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- our ability to retain subjects who have enrolled in a clinical study but may be prone to withdraw due to the rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest;
- the size of the potential markets for our rare disease product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Even if we complete clinical testing and receive approval from the FDA or applicable foreign agencies for QTORIN rapamycin, the FDA or the equivalent foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post- market clinical trials, or impose restrictions on the product's distribution in the form of a REMS. The FDA or the equivalent foreign regulatory authority may also approve QTORIN rapamycin for a more limited indication or a narrower patient population than we originally requested. In addition, the FDA or the equivalent foreign regulatory authority may not approve QTORIN rapamycin with the labeling that we believe is necessary or desirable, or may approve it with labeling that includes warnings or precautions or limitations of use that may not be desirable, for the successful commercialization of QTORIN rapamycin.

The factors outlined above, many of which are beyond our control, could cause us to experience significant delays or affect our ability to obtain regulatory approvals or commercialize QTORIN rapamycin. If we are unable to obtain regulatory approval and successfully commercialize our product candidates, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue to continue our business.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would adversely impact our potential to generate revenue, our business and our results of operations.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in any jurisdiction until it receives the requisite marketing approval from the applicable regulatory authorities of such jurisdictions. To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with preclinical, manufacturing and clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication applied for in the applicable regulatory filing. The approval process is typically lengthy and expensive, and approval is never certain.

We expect to report top-line data from our Phase 3 trial of QTORIN rapamycin for the treatment of microcystic LM in the first quarter of 2026. Data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their drugs.

The FDA or any foreign regulatory authorities can delay, limit or deny approval of QTORIN rapamycin for the treatment of microcystic LM or any future product candidates for many additional reasons, including:

- the FDA or other equivalent foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- Our inability to demonstrate to the satisfaction of the FDA or the equivalent foreign regulatory authority that any of our product candidates are safe and effective for the requested indication;
- the results of our clinical trials may not meet the level of statistical significance or clinical meaningfulness or establish an acceptable benefit-risk profile required by the FDA or other equivalent foreign regulatory authorities for marketing approval;
- the FDA or other equivalent foreign regulatory authorities may not accept data generated from our clinical trial sites;
- the FDA or other equivalent foreign regulatory authorities may find the chemistry, manufacturing and controls, or "CMC", data insufficient to support the quality of our product candidates;
- the FDA or other equivalent foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our CMOs;
- the FDA or other equivalent foreign regulatory authorities may disagree with our assessment that the delivery device component associated with our QTORIN platform is a Class I device exempt from premarket notification requirements as well as Quality System Regulation;

- the FDA or equivalent foreign regulatory authorities may not approve the formulation, dosing, labeling or specifications; or
- the potential for approval policies or regulations of the FDA or the equivalent foreign regulatory authorities to significantly change in a manner rendering our data insufficient for approval or invalidated.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which could materially adversely affect our business, financial condition, results of operations and prospects.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results and are not necessarily indicative of final results. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through earlier clinical trials. The results of nonclinical studies and early clinical trials of QTORIN rapamycin or any future product candidates may not be predictive of the results of later-stage clinical trials. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. For example, we announced topline results from our Phase 2 study of QTORIN rapamycin in patients with microcystic LM where, as is common in Phase 2 studies, efficacy was evaluated as secondary endpoints without multiplicity adjustment or statistical analyses, and the results from this study may not be predictive of results in our ongoing Phase 3 study in microcystic LM where a single hypothesis will be tested as the primary endpoint. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Moreover, even though we are using and plans to use the same formulation of QTORIN rapamycin to support multiple investigational development programs in multiple product candidates, it cannot be certain that any success we have with respect to the development of QTORIN rapamycin for the treatment of microcystic LM or for the treatment of cutaneous venous malformations will lead to the successful development of additional product candidates.

In addition, the design of a pivotal clinical trial can determine whether our results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing and conducting clinical trials and we may be unable to successfully design and execute a clinical trial to support regulatory approval.

We are currently conducting a Phase 3 clinical trial of QTORIN rapamycin for the treatment of microcystic LM, for which it expects to report top-line data in the first quarter of 2026. Even if the trial design in our Phase 3 clinical trial of QTORIN rapamycin for the treatment of microcystic LM proves successful, we may be unable to duplicate these results in other clinical trials we may conduct. Additionally, even if the FDA or other regulatory authorities accept the novel clinical endpoints we establish in connection with our Phase 3 trial in microcystic LM, there are no assurances that the FDA or other regulatory authorities will find the efficacy endpoints we propose in our future pivotal clinical trials to be sufficiently developed and tested and clinically meaningful, or that our product candidates will achieve the pre-specified endpoints in future pivotal clinical trials to a degree of statistical significance. For example, the FDA has commented that a placebo-controlled trial or additional trials assessing different clinical endpoints may be required to assess the efficacy of QTORIN rapamycin for the treatment of microcystic LM.

The rare genetic skin diseases we are currently targeting have no FDA-approved therapies, which subjects the design and execution of our clinical development program to complexities and known and unknown risks, including those related to novel and/or subjective clinical endpoints and varying patient population characteristics.

There are currently no FDA-approved therapies indicated for the treatment of microcystic LM or cutaneous venous malformations. We have concentrated our current research and development efforts on developing effective therapies for these indications, in addition to other rare genetic skin diseases and rare genetic conditions in other disease areas, and our future success depends on the success of this approach. The clinical trial requirements of the FDA and other comparable regulatory agencies and the criteria these regulators use to determine the safety and efficacy of any product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product. Given the nature of the genetic skin diseases we are targeting, the design and execution of our clinical development program is subject to both known and unknown risks.

As with QTORIN rapamycin for the treatment microcystic LM or cutaneous venous malformations and any future product candidates that may require us to use new or novel endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results. Even if applicable regulatory authorities do not object to our proposed endpoints in an earlier-stage clinical trial, such regulatory authorities may require evaluation of additional or different clinical endpoints in later-stage clinical trials or may not accept the clinical endpoints evaluated in later-stage clinical trials. For example, while the primary endpoint in the Phase 3 clinical trial of QTORIN rapamycin for the treatment of microcystic LM employs a dynamic assessment that uses a comparative rating scale, which was also assessed as one of several efficacy endpoints in the Phase 2 study in microcystic LM, the FDA has recommended that primary efficacy in the treatment of microcystic LM be evaluated on a static multicomponent assessment scale but recommended that we provide a rationale for selecting the comparative rating scale should we proceed with a comparative rating scale. If the FDA does not agree with Our primary endpoint, the FDA may instead consider the Phase 3 clinical trial's key secondary endpoint, which is a static multicomponent assessment scale, as pivotal to assessing efficacy, if alpha-protected. Alternatively, the FDA may consider the study to not be adequate and well-controlled and could request additional clinical trials to assess a static multicomponent assessment scale as the primary endpoint. As a result, the design and conduct of our ongoing clinical trials and any future product candidates may take longer, be more costly or be less effective.

Further, different results may be achieved depending upon the characteristics of the population enrolled in our studies and which analysis population is used to analyze results. As a result, there is no guarantee that our clinical trials will produce statistically significant results with respect to subject-reported outcomes, and there can be no guarantee that the characteristics of the population enrolled in our clinical trials does not adversely impact the results reported for such trials.

Any delays in, or the denial of, approval of any of our product candidates resulting from our inability to establish effective trial designs for rare genetic skin diseases could materially adversely affect our business, financial condition, results of operations and prospects.

Our lead product candidates are based on our QTORIN platform and it is highly dependent on the successful development of this novel and unproven technology.

Our proprietary QTORIN platform was developed over several years of research to overcome inherent challenges, including chemical stability, skin penetration and skin distribution, with topical delivery of mTOR inhibitors, such as rapamycin and other therapeutic agents. QTORIN is an anhydrous gel comprising excipients intentionally selected in a ratio designed to achieve drug stability at room temperature and enable cutaneous distribution of therapeutics levels of cargoes into the target cells in the basal layer of the epidermis and to the dermis. Our product candidate for the treatment of microcystic LM and the treatment of cutaneous venous malformations leverages QTORIN as a mechanism of delivery of a 3.9% concentration of rapamycin to treat the applicable disease.

QTORIN is the platform for our current clinical-stage product candidates and for other research-stage product candidates in our pipeline, and accordingly, our future success depends in significant part on the successful development of this novel technology. Negative results in the development of QTORIN rapamycin for either the treatment of microcystic LM or cutaneous venous malformations may also impact our ability to obtain regulatory approval for other product candidates which we expect to develop based on our QTORIN platform, either at all or within anticipated timeframes because, although we may be targeting different indications, the underlying technology platform is the same for each product candidate and there may be commonalities in the manufacturing and development processes. Accordingly, a failure in any one QTORIN-based program may decrease trust in our technology and affect our ability to conduct clinical programs for other QTORIN-based product candidates.

We have not yet succeeded and may not succeed in completing clinical development of or obtaining regulatory approval for any of our product candidates using QTORIN. As a result, it is more difficult for it to predict whether the application of our QTORIN platform, or any similar or competitive platforms, will result in the development and marketing approval of any products. Any developmental problems we experience in the future related to our QTORIN platform or any of our research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or clinical trials or commercializing any product candidates we may develop on a timely or profitable basis, if at all, which could materially adversely affect our business, financial condition, results of operations and prospects.

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

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit subjects to participate, as well as the completion of required follow-up periods. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to the biotechnology or pharmaceutical fields, competitive clinical trials for similar patient populations, the existence of current treatments or for other reasons outside of our control. The timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed, which could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether.

Importantly, the indications that we are currently targeting and may in the future target are rare diseases, which may limit the pool of subjects that may be enrolled in our ongoing or planned clinical trials. To the extent our clinical trials are limited to specific genotypes, the population of eligible trial participants is even further limited. Microcystic LM affects an estimated greater than 30,000 diagnosed patients in the United States. Cutaneous venous malformations affect an estimated greater than 75,000 people in the United States. Some of the other diseases we intend to target have similarly limited patient populations. We expect to rely in part on our relationships with patient advocacy groups to assist in identifying eligible patients, and any deterioration of those relationships could impede our ability to successfully enroll patients in our clinical trials. We may not be able to initiate or continue clinical trials for our product candidates if it is unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States.

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

- size and nature of the target population and the process for identifying subjects;
- design of the trial protocol;
- eligibility and exclusion criteria for the trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials for similar product candidates or targeting subjects meeting our trial eligibility criteria;
- severity of the disease under investigation;
- availability of genetic testing for potential patients;
- proximity and availability of clinical trial sites for prospective subjects;
- ability to obtain and maintain subject consent;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

If we have difficulty enrolling a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We may be unable to obtain Orphan Drug Designation for certain of our product candidates and, even if it obtains such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating disease affecting not more than five in 10,000 persons. Additionally, Orphan Drug Designation is granted by the EMA for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic disease and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product.

We have received Orphan Drug Designation for QTORIN rapamycin for the treatment of microcystic LM from the FDA and EMA. If we request Orphan Drug Designation or the foreign equivalent for any of our other or future product candidates, there can be no assurances that the FDA or foreign regulatory authorities will grant any of our product candidates such designation. Additionally, the designation of any of our product candidates as an orphan product does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant Orphan Drug Designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an Orphan Drug Designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before We do (regardless of our Orphan Drug Designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period unless FDA concludes that our drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. The applicable exclusivity period is seven years in the United States and 10 years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for Orphan Drug Designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same disease if the FDA concludes that the latter drug is not the same drug or is clinically superior. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if the second applicant can establish in our application that our medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior; if the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or if the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Our inability to obtain Orphan Drug Designation or the foreign equivalent for our product candidates, or to realize the benefits of such designation, could have an adverse effect on our business, financial condition, results of operations and prospects.

We are targeting rare genetic skin diseases, and the small patient populations associated with such diseases present additional risks with respect to clinical development, regulatory approvals and commercialization of product candidates.

Our approach of targeting genetic skin diseases present risks related to the clinical development, regulatory approval and commercialization of our product candidates, including the following:

- we may be difficult to establish safety and efficacy in these types of patient populations given there is less known of the natural history of the disease;
- we expect to face challenges with respect to patient enrollment in our clinical trials, as described above;
- small sample sizes in our clinical trials suggest that we face the risk of substantial variability in the results of our trials, and so the outcome of nonclinical testing and early clinical trials is less likely to be predictive of the success of later-stage clinical trials;
- following approval of our product candidates, if any, pricing and level of reimbursement may not be sufficient to offset costs of development, manufacturing, marketing, and commercialization; and
- market size is a significant variable in disease indications classified as rare. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient advocacy groups or market research. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product candidates we may develop or may become increasingly difficult to identify or gain access to. Accordingly, even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Adverse developments with respect to any of the foregoing could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our development and commercialization strategy for our product candidates depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of rapamycin. If we are not able to pursue this strategy, we may be delayed in receiving regulatory authority approval.

The Hatch-Waxman Amendments added Section 505(b)(2) to the U.S. Federal Food, Drug, and Cosmetic Act, or "FDCA". Section 505(b)(2) permits the submission of an NDA, where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature and/or the FDA's previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any deviation from the previously approved product and to justify that it is scientifically appropriate to rely on the applicable published literature or referenced product, referred to as bridging. The FDA may then approve the new product candidate for all or some of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant, if such approval is supported by study data. The labeling, however, may be required to include all or some of the limitations, contraindications, warnings or precautions or restrictions on use included in the reference product's labeling, including a boxed warning, or may require additional limitations, contraindications, warnings or precautions or restrictions on use.

We currently plan to pursue marketing approval for QTORIN rapamycin for several indications in the United States through Section 505(b)(2) NDAs and will be completing bridging analyses comparing QTORIN rapamycin to the approved oral rapamycin product, a previously approved organ rejection prophylactic, prior to NDA submission. If the FDA disagrees with our conclusions regarding the appropriateness of our reliance on the FDA's prior findings of safety and efficacy for the approved oral rapamycin productor on published literature, or if we are not otherwise able to bridge to the listed drug or published literature to demonstrate that our reliance is scientifically appropriate, we could be required to conduct additional nonclinical toxicology, clinical safety or efficacy trials, or other studies to support our NDA, which could lead to unanticipated costs and delays or to the termination of our development programs. For example, while we plan to bridge QTORIN rapamycin and the approved oral rapamycin product based on cross-study comparison between pharmacokinetic data from the prescribing information for the approved product, the FDA recommends that bridging to support an NDA for the treatment of microcystic LM be done in a relative bioavailability study comparing the pharmacokinetics of a topical product applied under maximal use conditions and the approved oral drug. The planned cross study analysis allows for comparison of systemic pharmacokinetic parameters, key criteria for assessing the applicability of safety findings from the listed drug, which are a result of systemic exposure from the oral formulation. If the FDA does not agree with our pharmacokinetic approach, we may need to conduct a relative bioavailability study, which compares direct assessment of pharmacokinetics of both products administered under similar conditions. For example, FDA may request different specific criteria for comparisons that cannot be evaluated based on limitations in the pharmacokinetic data available in the prescribing information of the approved drug. If we are unable to obtain approval for our product candidates through the Section 505(b)(2) NDA process, we may be required to pursue the more expensive and time consuming 505(b)(1) approval process, which consists of full reports of investigations of safety and effectiveness conducted by or for the applicant. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway to FDA approval, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

The validity, scope and enforceability of any patents that we may list in the Orange Book that cover QTORIN rapamycin, if approved by the FDA for any indication, can be challenged by competitors.

If QTORIN rapamycin is approved by the FDA for any indication, one or more third parties may challenge the patents covering QTORIN rapamycin with respect to such indication, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or "ANDA", for a generic drug bioequivalent to our QTORIN rapamycin, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. Alternatively, a third party that files an ANDA for a generic drug bioequivalent to QTORIN rapamycin may elect to submit a "section viii" statement certifying that our proposed label does not contain (or carves out) any language regarding the patented method of use rather than certify to a listed method of use patent. This section viii statement does not require notice to the patent holder or NDA owner. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If We do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

Other companies could receive FDA approval for a topical rapamycin product before we receive FDA approval for QTORIN rapamycin for microcystic LM or cutaneous venous malformations, and thus could be granted regulatory exclusivity that could significantly delay our ability to receive approval for and commercialize our QTORIN rapamycin and therefore dramatically reduce our market potential.

Other companies may submit a Section 505(b)(2) NDA and receive approval for a topical rapamycin product candidate prior to the approval of our NDA for QTORIN rapamycin for the treatment of microcystic LM or for other indications we are pursuing or may pursue in the future. The first approved Section 505(b)(2) product for a particular condition of use or change to a marketed product, such as a new formulation for a previously approved product, may be granted three-year exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. The grant of three-year exclusivity can delay the FDA's approval of other Section 505(b)(2) applicants for the same condition of use or change to the drug product, such as the first approval of a topical formulation of rapamycin, that was granted exclusivity, regardless of the date of submission of each NDA.

We believe that other companies are developing topical rapamycin products. In order to obtain regulatory approval with a Section 505(b)(2) NDA, other companies would have to sponsor or conduct new clinical investigations (other than bioavailability studies) that are essential to approval of the application, as well as conduct the required bridging studies. If the FDA approves another company's Section 505(b)(2) NDA for our topical rapamycin product, even for another indication, and grants the other company three-year exclusivity before we receive approval for QTORIN rapamycin for the treatment of microcystic LM, the FDA may be precluded from approving any NDA we may submit with respect to QTORIN rapamycin until after that three-year exclusivity period has expired unless we pursue the more expensive and time consuming 505(b)(1) approval process, which would likely require that we sponsors or conducts additional nonclinical and/or clinical studies. For example, upon approval of a Section 505(b)(2) NDA for the treatment of facial angiofibroma associated with tuberous sclerosis, Hyftor, a topical gel product containing sirolimus (also known as rapamycin), received three years of new product exclusivity. If another rapamycin topical product were to receive three-year exclusivity for a condition of use that overlaps with QTORIN rapamycin, approval of QTORIN rapamycin would be delayed until the expiration of such exclusivity.

It is also not uncommon for a sponsor of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Any such delay could dramatically reduce our expected market potential for our QTORIN rapamycin for any disease indication and could materially adversely affect our business, financial condition, results of operations and prospects.

Serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

As we continue our development of our product candidates and initiate additional preclinical studies or clinical trials of these or future product candidates, if any, serious adverse events, unacceptable levels of toxicity, undesirable side effects or unexpected characteristics may emerge. Although we have designed QTORIN rapamycin for topical application and in a manner that it believes will not result in systematic absorption, systematic exposure to rapamycin, the active ingredient in our lead product candidate, at levels consistent with the approved oral dosage form, is known to result in significant adverse reactions, including peripheral edema, hypertriglyceridemia, hypertension, hypercholesterolemia, creatinine increases, abdominal pain, diarrhea, headache, fever, urinary tract infection, anemia, nausea, arthralgia, pain and thrombocytopenia. Investigators may attribute infectious diseases occurring during clinical trials of QTORIN rapamycin to suspected or possible immunosuppression, based on the systematic mechanism of action of rapamycin. Further, we have conducted and continues to conduct open-label studies of QTORIN rapamycin and, without a concurrent control arm, adverse events may be attributed to QTORIN rapamycin that may be a result of background disease or other external factors. Other active pharmaceutical ingredients we select for our product candidates may have similar adverse event profiles. The emergence of any such serious adverse events, unacceptable levels of toxicity, undesirable side effects or unexpected characteristics could cause difficulty recruiting and retaining participants for our trials or it may abandon these product candidates, institute burdensome monitoring programs or limit their development to more narrow uses, less frequent dosing, lower potency levels or subpopulations in which the serious adverse events, unacceptable levels of toxicity, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. The FDA or an IRB, or equivalent foreign regulatory authorities, may also require that we suspend, discontinue, or limit our clinical trials based on safety information or that there is inadequate prospect of treatment benefit. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if one or more of our product candidates receive marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings, precautions, or limitations of use in the labeling;

- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to implement a REMS;
- we may be required to conduct additional clinical trials as post-marketing requirements;
- we could be sued and held liable for harm caused to patients; and
- our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, which could materially adversely affect our business, financial condition, results of operations and prospects.

Fast Track Designation granted for QTORIN rapamycin for the treatment of microcystic LM and, if granted, for any of our other product candidates by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We were granted Fast Track Designation by the FDA for QTORIN rapamycin for the treatment of microcystic LM and may seek such designation for QTORIN rapamycin for other indications, and for any other product candidates. If a drug is intended for the treatment of a serious or life-threatening disease and the drug demonstrates the potential to address unmet medical needs for this disease the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, it cannot assure you that the FDA would decide to grant it. Even if We do receive Fast Track Designation, as we have for QTORIN rapamycin for the treatment of microcystic LM, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development programs. Many drugs that have received Fast Track Designation have failed to obtain approval.

Breakthrough Therapy Designation granted for QTORIN rapamycin for the treatment of microcystic LM and, if granted, for any of our other product candidates by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We were granted Breakthrough Therapy Designation by the FDA for QTORIN rapamycin for the treatment of microcystic LM and may seek such designation for QTORIN rapamycin for other indications, and for any other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for designation.

Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or top-line data we previously published. For example, we expect to report top-line data from our Phase 3 clinical trial for the treatment of microcystic LM in the first quarter of 2026, but any such data may change following further auditing. As a result, preliminary and top-line data should be viewed with caution until the final data are available. If the interim, top-line, or preliminary data that we reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, it focuses on research programs and product candidates that it identifies for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause it to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If We do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for it to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our product candidates during or after approval for a variety of reasons, including the appearance of new technologies that render our product obsolete, competition from a competing product or changes in or inability to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

If we seek to market any product candidates in our pipeline in countries other than the United States, it will need to comply with the regulations of each country in which it seeks to market our products. Additionally, although our trials are currently being conducted in the U.S., we may conduct clinical trials for our product candidates at clinical trial sites outside the U.S. and the FDA and equivalent foreign regulatory authorities may not accept data from such sites.

None of our product candidates are currently approved for sale by any government authority. If we fail to comply with regulatory requirements in any market it decides to enter, or to obtain and maintain required approvals, or if regulatory approvals in the relevant markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates, if approved, will be harmed. Marketing approval in one jurisdiction, including the United States, does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain a marketing approval in countries in which we seek to market our products or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for any of our products. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries.

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

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available procedures. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Commercialization of Our Product Candidates, if Approved

Even if QTORIN rapamycin or any future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if QTORIN rapamycin for the treatment of microcystic LM or for the treatment of cutaneous venous malformations or any future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, patient advocacy groups, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may never be able to generate adequate product revenue or become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety, efficacy, risk-benefit profile and potential advantages compared to alternative or existing treatments, which include, with respect to microcystic LM,
- surgery, sclerotherapy, laser and, cryotherapy, any of which physicians may perceive to be adequately effective or to present less risk for some or all patients;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies over existing treatment alternatives;
- support from patient advocacy groups;

- side effects that may be attributable to our product candidates and the difficulty of or costs associated with resolving such side effects;
- the timing of market introduction of our product candidates as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of our product candidates in the labeling approved by regulatory authorities, including boxed warnings, contraindications, or a REMS, which may not be required of alternative treatments and competitors' products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the effectiveness of our sales, marketing and market access efforts;
- the cost of treatment in relation to alternative treatments or methods of symptom management;
- Our ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- publicity relating to our product candidates or those of our competitors;
- the availability of third-party coverage and adequate reimbursement at any given price level of each of our product candidates and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- utilization controls imposed by third-party payors, such as prior authorizations and step edits.

We cannot assure you that our current or future product candidates, if approved, will achieve market acceptance among physicians, patients, patient advocacy groups, third-party payors or others in the dermatological community necessary for commercial success. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success could materially adversely affect our business, financial condition, results of operations and prospects.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates if approved, we may not be able to generate product revenue.

We have never commercialized a product. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization. We do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market QTORIN rapamycin or any other product candidate, if approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

We believe that it will be able to commercialize QTORIN rapamycin for the treatment of microcystic LM, if approved, with a specialized sales force that targets a focused subset of medical dermatologists, and is supported by sales management, medical liaisons, market access, an internal marketing group, and distribution support. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Other factors that may inhibit our efforts to commercialize our product candidates, once approved, include:

- the inability to recruit and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to maintain our collaborative relationships with patient advocacy groups and leverage those relationships to increase patient identification and outreach and the rate of new patient acceptance of our product candidates;

- our inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding rare diseases and our future products;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- limitations of use, contraindications, or warnings, including boxed warnings, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agrees as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put it 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 or engaging a contract sales organization.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, it will not be successful in commercializing any of our product candidates, if approved, and will not become profitable. We may be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States or in any markets outside of the United States, our revenues from product sales and our profitability, if any, may be lower than if we were to market, sell and distribute any products that we develop ourself in all such territories. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates, if approved, or may be unable to do so on terms that are acceptable to it. We may 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 sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, it will not be successful in commercializing our product candidates, if approved.

Our estimated market opportunities for our product candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited.

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, including patient advocacy groups, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot assure you of our accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. While we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this "*Risk Factors*" section. If these third-party or internally generated data prove to be inaccurate or we make errors in our assumptions based on that data, our actual market may be more limited than our estimates. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business. The estimates of our addressable patient populations included in this prospectus should not be taken as indicative of our ability to grow our business. For more information regarding the estimates of patient populations included in this prospectus, see the sections titled "*Market and Industry Data*" and "*Business—Our Pipeline*."

The size of the markets for our product candidates have not been established and may be smaller than it estimates.

Our estimates of the annual total addressable markets for our product candidates are based on internal and third-party estimates, including, without limitation, estimated incidence and prevalence of these diseases, and estimated annual price per patient for our product candidates. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our product candidates may prove to be incorrect. If the annual total addressable markets for our product candidates are smaller than we have estimated, this may have an adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which it receives regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Because there are currently no products approved for the treatment of microcystic LM, the pricing and reimbursement of our product candidates, if approved, is uncertain. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with our prescription or creating coverage uncertainties for prescribers and patients. Moreover, our target patient populations are small, as a result of which the pricing and third-party payor reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. Eligibility for reimbursement does not imply that a medical product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected.

Patients who are prescribed medicine for the treatment of their diseases generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. If any of our product candidates fail to demonstrate attractive efficacy and safety profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate, particularly given the small patient populations for our targeted indications, or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could materially adversely affect our business, financial condition, results of operations and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, thus rendering our products non-competitive, obsolete or reducing the size of our market.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

In addition, some of the market demand for topical rapamycin may be satisfied by state-licensed compounding pharmacies operating under Section 503A of the FDCA. Although such pharmacies will be unable to compound any drug that is essentially a copy of QTORIN rapamycin, if approved, a compounded product would not be considered a copy of QTORIN rapamycin if there were a difference between the FDA-approved product and the compounded product that was made for an individual patient and which the prescribing practitioner determines produces a significant difference for that patient. Physicians may determine that such differences exist for some or all of their patients and may choose to prescribe compounded rapamycin because it would be a component of an FDA-approved drug product (specifically QTORIN). If the FDA-approved drug product is not commercially available and thus added to the FDA's published drug shortage list, compounders also would be able to copy it without the necessity of noting a significant difference between the compounded formulation and the FDA-approved drug In the event compounders engage in the compounding of rapamycin products following FDA approval of QTORIN rapamycin, we could be subject to significant competition from those compounded formulations.

The companies against which we may compete may 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 it does. 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 necessary for, our programs. 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 any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ourselves, which could result in our competitors establishing a strong market position before it is able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Because of our primary focus on rare diseases, if our product candidates achieve marketing approval, it expects to seek premium pricing.

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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that it will be subject to additional risks related to conducting marketing and sales activities in international jurisdictions and entering into international business relationships, including:

- different regulatory requirements for approval of drugs in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- the need to seek additional patent approvals, licenses to patents held by third parties and/or face claims of infringing third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA, the U.K. Bribery Act 2010 or other comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including pandemics, or other outbreaks of infectious disease, earthquakes, typhoons, floods and fires.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Business and Operations

We will need to increase the size of our organization, and we may experience difficulties in executing our growth strategy and managing any growth, including with respect to any acquired businesses, therapeutic candidates or technologies.

As of December 20, 2024, we had nine full-time employees. Our management and personnel, systems and facilities currently in place are not adequate to support our future growth. We will need to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities, commercialize our lead product candidates or any future product candidates and operate as a public company. In order to effectively execute our growth strategy, we will need to identify, recruit, retain, incentivize and integrate additional employees in order to expand our ability to:

- manage our clinical trials effectively;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties;
- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners; and
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels.

Should we in the future acquire any complementary business, therapeutic candidates or technologies, our ability to integrate and manage acquired businesses, therapeutic candidates or technologies effectively will depend upon a number of factors including the size of the acquired business, the complexity of any therapeutic candidate or technology and the resulting difficulty of integrating the acquired business's operations, if any. Our relationship with current employees or employees of any acquired business may become impaired. We may also be subject to unexpected claims and liabilities arising from such acquisitions. These claims and liabilities could be costly to defend, could be material to our financial position and might exceed either the limitations of any applicable indemnification provisions or the financial resources of the indemnifying parties. There can also be no assurance that we will be able to assess ongoing profitability and identify all actual or potential liabilities of a business, therapeutic candidate or technology prior to our acquisition. If we acquire businesses, therapeutic candidates or technologies that result in assuming unforeseen liabilities in respect of which it has not obtained contractual protections or for which protection is not available, this could materially adversely affect our business, financial condition, results of operations and prospects.

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are unable to successfully identify, recruit, retain, incentivize and integrate additional employees and otherwise expand our managerial, operational, finance and other resources, our business and operational performance will be materially and adversely affected.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future product candidates, commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including Wesley H. Kaupinen, our Chief Executive Officer, Kathleen Goin, our Chief Operating Officer, and Jeffrey Martini Ph.D., our Chief Scientific Officer. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product candidates and otherwise negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We maintain "key person" insurance only for our Chief Executive Officer.

Our employment agreement with Mr. Kaupinen may be terminated immediately by us for cause or by Mr. Kaupinen with good reason, or upon thirty days' notice if terminated for any other reason. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees and key consultants of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the eastern Pennsylvania area where it is headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist it in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our product candidates and may have to limit our commercialization if we obtain regulatory approval.

The use of our product candidates in clinical trials, and the sale of any of our product candidates for which it obtains regulatory approval, exposes us to the risk of product liability claims. Product liability claims might be brought against it by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, we may be sued if any product candidate it develops allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our product candidates for which it obtains regulatory approval. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, product liability claims may result in:

- loss of revenue from decreased demand for our product candidates, if approved;

- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- exhaustion of any available insurance and our capital resources;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates, if approved;
- significant negative media attention;
- decrease in our stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

We currently hold $5.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as it initiates additional clinical trials. We will need to further increase our insurance coverage if it commences commercialization of any of our product candidates for which it obtains marketing 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. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and our prospects.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and it cannot anticipate all of the ways in which the political or economic climate and financial market conditions could materially adversely affect our business, financial condition, results of operations and prospects.

Our business and operations would suffer in the event of system failures, and it faces risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.

Our information security systems and internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development and, if such product candidates are approved, commercialization programs.

Additionally, our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to the company's systems using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain personal data. Data breaches could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities, including various domestic and international privacy and security regulations.

The legislative and regulatory landscape for privacy and data protection continues to evolve. In the United States, certain states may adopt privacy and security laws and regulations that may be more stringent than applicable federal law. For example, California enacted the CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. We may also in the future be subject to data protection laws and regulations of other jurisdictions, such as the EU's GDPR, which provides data subjects with certain rights and requires organizations to adopt technical and organizational safeguards to protect personal data. In the event that we are subject to or affected by privacy and data protection laws, including the CCPA or GDPR and other domestic or international privacy and data protection laws, we may expend significant resources to comply with such laws, and any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

If we or our third-party contractors fail to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Although we maintain workers' compensation insurance to cover it for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Even if we receive regulatory and marketing approval of our product candidates, it will be subject to extensive and ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals or other marketing authorizations we obtain for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our drug product candidates, such as QTORIN rapamycin for the treatment of microcystic LM, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or an equivalent foreign regulatory authority authorizes our product candidates for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and good clinical practices, or "GCP", requirements for any clinical trials that we conducts post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our CMOs or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning or untitled letters, Form 483s, or holds on clinical trials;
- refusal by the FDA to accept new marketing applications or supplements, approve or otherwise authorize for marketing pending applications or supplements to applications filed by us or suspension or revocation of approvals or other marketing authorizations;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our product candidates, if authorized for marketing, may cause or contribute to adverse medical events that we are required to report to the FDA, and if it fails to do so, it would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our product candidates, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, if such products are marketed, could have a negative impact on us.

With respect to any of our product candidates in clinical testing or approved by the FDA, we will be subject to the FDA's safety reporting requirements. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our approval or delay in approval of future products.

We may choose to voluntarily recall a product if any material deficiency is found. A recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls involving our product candidates, if and when they are approved or otherwise authorized for marketing, could materially adversely affect our business, financial condition, results of operations and prospects.

We will be subject to healthcare laws and regulations relating to our business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how it researches, markets, sells and distributes any products for which it obtains marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for the purchase, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Law, which prohibit, among other things, impose criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the U.S. government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA and its implementing regulations, which impose criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH Act, and their respective implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates and their subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the federal Physician Payments Sunshine Act, also known as Open Payments program, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or "CMS", information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives;
- state privacy laws and regulations, such as those of California, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, the CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; resulting in increased compliance costs and potential liability); and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to its business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; certain state and local laws that require the registration of pharmaceutical sales representatives; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with and/or ownership interests by physicians and other healthcare providers, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to it, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could materially adversely affect our business, financial condition, results of operations and prospects.

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

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could materially adversely affect our business, financial condition, results of operations and prospects.

Healthcare reform measures may increase the difficulty and cost for us to successfully commercialize our product and product candidates, if approved, and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities relating to our product and product candidates, if approved, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing authorizations of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing authorization, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs of pharmaceuticals. There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products, which has resulted in several presidential executive orders, Congressional inquiries, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and Medicaid, and reform government program reimbursement methodologies for drug products. For example, on August 2, 2011, the Budget Control Act of 2011 imposed, subject to certain temporary suspension periods, 2% reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including an alternative rebate calculation for line extensions that is tied to the price increases of the original drug, and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs is eliminated. Elimination of this cap may, in some cases, require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products.

Recently, several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act, or "IRA", in August 2022, which, among other things, allows the Department of Health and Human Services, or "HHS", to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) are eligible to be selected for negotiation by CMS, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products begin in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will represent a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in litigation. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of our product candidates, if approved.

We expect that the IRA, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our product and product candidates, if approved.

Any product candidates for which we are able to obtain regulatory approval in the future may become subject to unfavorable pricing regulations, third-party payor coverage and reimbursement policies, or healthcare reform initiatives.

Our ability to commercialize any of our other product candidates, if approved, successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government payor programs at the federal and state level, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications or procedures. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement for a product or procedure may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our product candidates, if approved, may be difficult. We may be required to conduct expensive pharmacoeconomic studies to seek to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any of our other product candidates for which marketing approval is obtained.

As discussed above, the IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the HHS t, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and the requirement for manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions. Although the IRA exempts orphan drugs that treat only one rare disease from the drug price negotiation provisions, We do not know if additional drug pricing reforms could eliminate this exemption and therefore affect the prices it can charge and reimbursement it receives for our product candidates, if approved, thereby reducing our profitability. The full extent of the IRA on our business and the pharmaceutical industry in general is not yet known.

Future efforts to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates. We cannot provide any assurances that it will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other equivalent foreign regulatory authorities strictly regulate the marketing of and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other equivalent foreign regulatory authorities as reflected in the product's approved labeling. In addition, although we believe our product candidates may exhibit a lower risk of side effects or more favorable tolerability profile or better symptomatic improvement than other products for the indications we are studying, without head-to-head data, we will be unable to make comparative claims for our product candidates, if approved. If we receive regulatory approval for any of our product candidates and are found to have promoted any of our products for off-label uses, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, it could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged. The FDA has also previously requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, it could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates, once approved, as he or she may deem appropriate in his or her medical judgment even if such use falls outside of the scope of the approved indications. Physicians may also misuse our product candidates or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of our product candidates for indications other than those approved by the FDA and/or other regulatory authorities may not effectively treat such diseases which could harm our brand and reputation among both physicians and patients.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete outside of the U.S. market and subject it to liability if it violates them.

If we expand our operations outside of the United States, it must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which it operates. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, financial condition, results of operations and prospects.

In addition, our products and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Reliance on Third Parties

We currently rely on CMOs to manufacture preclinical and clinical supplies of our product candidates and will rely on CMOs for the commercial supplies of any approved product candidate. The loss of these manufacturers, or their failure to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not currently have nor does it plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and it lacks the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. Instead, we currently rely on CMOs to manufacture preclinical and clinical supplies of our product candidates and the commercial supplies of any approved product candidate. We have agreements with Altasciences and PMRS, both, cGMP facilities to manufacture clinical supply of our product candidate for clinical trials and for the manufacture of commercial supply of our QTORIN rapamycin, if approved. Additionally, we have agreements with Medpharm UK for the manufacture of our clinical supply of our product candidate for clinical trials. We plan to enter into an agreement with another CMO for our supply of QTORIN rapamycin and qualify them as our second source of clinical and commercial supply. Please see "*Business—Manufacturing*" for a discussion of our current manufacturing and supply agreements.

Reliance on CMOs entails risks to which we may not be subject if we manufactured product candidates ourselves, including:

- the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- reliance on the third party for regulatory compliance and quality control and assurance and failure of the third party to comply with regulatory requirements;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications);
- a disruption to one or more of our CMOs' relevant operations; the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or vehicle not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the risk that our CMOs face financial difficulties or declare bankruptcy; and
- the possibility of our failure to enter into agreements for manufacturing services, on commercially reasonable terms or at all, or the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us

Moreover, there are a limited number of manufacturers capable of producing our product candidates, which exposes it to the risk of disruption in the supply of product candidates for our preclinical studies and clinical trials, and if approved, ultimately for commercial sale. In the case of QTORIN rapamycin which we are currently developing for both the treatment of microcystic LM and the treatment of cutaneous venous malformations, there is a limited number of manufacturers that will work with an active pharmaceutical ingredient, such as rapamycin, that has immunosuppressant properties. If our third-party manufacturing agreements were to be terminated for any reason, we may be unable to procure alternative manufacturers for clinical or commercial manufacture of QTORIN rapamycin, as applicable, on a timely basis or at all.

Additionally, while we have entered into agreements with Altasciences and PMRS for the commercial manufacture of our product candidates, both organizations must complete a scale-up process that includes the completion of various technical and regulatory steps before it will be able to produce commercial supply of our QTORIN rapamycin. If both CMOs fail for any reason to carry out our contractual duties or otherwise fails to meet our manufacturing requirements prior to our completion of the process of qualifying our second source manufacturer, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We may be unable to enter into additional agreements with third-party manufacturers or suppliers or do so on favorable terms. Our anticipated reliance on a limited number of third party-manufacturers or suppliers exposes us to the following risks:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter or other enforcement action by the FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of proprietary information, including trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- carrier disruptions or increased costs that are beyond our control.

Failure to deliver our drugs under specified storage conditions and in a timely manner. If any of these risks materialize and impact our CMOs' ability to produce our product candidates, it will have no other means of producing our product candidates until the adverse impact is mitigated or us or they procure alternative manufacturing facilities or sources of supply. Though we carefully manage our relationships with our CMOs, there can be no assurance that we will not encounter challenges or delays in the future. The loss of any of our CMOs, or their failure to provide it with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

If the manufacturers upon whom we rely fail to produce our product candidates or components pursuant to the terms of contractual arrangements with us or fail to comply with stringent regulations applicable to pharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates, if approved, and may lose potential revenues.

We have agreements governing the activities of the CMOs which manufacturers our preclinical, clinical and commercial supply of our product candidates, and we expect to enter into agreements with additional CMOs in the future, but we have or will have limited influence and control over their actual performance and activities. If our CMOs do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with strictly enforced federal, state, and foreign regulations, or if there are disagreements between us and such parties, clinical development or marketing approval of our product candidates could be delayed.

All manufacturers of our product candidates and therapeutic substances must comply with cGMP requirements enforced by the FDA that are applicable to both finished products and their active components used both for clinical and commercial supply. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. The FDA enforces these requirements through our facilities inspection program. If the FDA determines that our manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve a marketing application until the deficiencies are corrected or until we replace the manufacturer in our application with a manufacturer that is in compliance. Our manufacturers will also be subject to continuing FDA and other regulatory authority inspections should we receive marketing approval for any of our product candidates. Any such deviations from the regulatory requirements of the FDA or other regulatory authorities may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we expect to have limited ability to control our manufacturers' compliance with these regulations and standards. A failure to comply with the applicable regulatory requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties. Depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in FDA approval or commercial launch of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates and could adversely affect our business.

We acquire the pumps we intend to use to dispense our QTORIN rapamycin, if approved, from a sole source supplier. If we experience an interruption in supply from this supplier, our business may be harmed.

We have an agreement with Nemera Le Tréport SAS, or "Nemera", a sole source supplier, for the pumps it intends to use to dispense QTORIN rapamycin, if approved. If there is an interruption in the supply of these pumps from Nemera due to pricing, timing, availability or other issues, if Nemera does not successfully carry out our contractual duties, meet expected deadlines or supply these pumps in accordance with the terms of our agreement and with applicable federal, state, and foreign regulations, or if there are disagreements between us and Nemera, clinical development, marketing approval or commercial manufacturing of our product candidates, if approved, could be delayed.

If our agreement with Nemera is terminated or if Nemera otherwise ceases to supply the pumps we intend to use to dispense QTORIN rapamycin, if approved, there is no guarantee that we will find an alternative supplier for the necessary packaging materials on terms acceptable to it, or at all. As a result, we would have to redesign our commercial packaging which would be subject to FDA review. This may cause delay in the commercialization of our product candidates and cause us to incur additional expense. The qualification process for a new vendor could take months or even years, particularly if we are unable to locate an alternative supplier that has sufficient regulatory qualifications, and any such delay in qualification could materially adversely affect our business, financial condition, results of operations and prospects.

We rely on third parties to conduct aspects of our nonclinical studies and our clinical trials. 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 QTORIN rapamycin for the treatment of microcystic LM or any other current or future product candidates.

We do not have the ability to independently conduct nonclinical studies and clinical trials. Although our employees manage the overall conduct of our preclinical studies and clinical trials and we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable regulations and the investigational plan and protocol, we rely on third parties, such as CROs and academic institutions, to conduct aspects of our preclinical studies and clinical trials of QTORIN rapamycin for the treatment of microcystic LM. The third parties with whom we contract for execution of our preclinical studies and 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 are not our employees, and we expect CROs, independent clinical investigators and consultants to play a significant role in the conduct of our trials and the subsequent collection and analysis of data. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators, CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving it marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. Our failure or the failure of third parties on whom we rely on to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing authorization process.

In addition, except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that our third party CROs, investigators, and institutions devote to our programs. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If a clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of our product candidates.

Our third parties may also have relationships with other commercial entities, some of which may compete with us. In some cases, these third parties could terminate their agreements with us without cause.

The execution of non-clinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. If the third parties conducting aspects of our clinical trials fail to communicate and coordinate with one another, 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 data they obtain is compromised due to the failure to adhere to our clinical trial protocols GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated, which would have a material adverse effect on our business.

We may rely on third parties to perform many essential services for any products that it commercializes. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of our product candidates, if approved, key aspects of which will be out of our direct control. These service providers may provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management, and cash collection. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver adequate product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage third parties to perform various other services for it relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, we could be subject to regulatory sanctions.

We may also contract with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or commits errors in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

Our future commercial collaborators, as well as our independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, suppliers, service providers and other vendors, may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other equivalent foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such foreign regulatory authorities; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or 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, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of 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 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 it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, 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 it is 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, disgorgements, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could materially adversely affect our business, financial condition, results of operations and prospects.

We intend to explore strategic collaborations with third parties for the development or commercialization of our product candidates, which collaborations may never materialize or may require that it relinquish rights to and control over the development and commercialization of our product candidates.

An element of our business strategy includes acquiring or in-licensing technologies or product candidates for the treatment of rare genetic skin diseases. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies, resources or markets. While we do not have a strategic collaboration in place with respect to QTORIN rapamycin and we intend to independently commercialize this product candidate in the United States, we may selectively seek collaborators to commercialize our products outside of the U.S. market.

At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, it will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies or for certain indications, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our current collaborators and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;

- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business;
- collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or
- require a new version of a product candidate for clinical testing;
- collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- collaborators may experience financial difficulties;
- collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

Additionally, if any future collaborator of we are involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminate our agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

Risks Related to Intellectual Property

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

We rely upon a combination of patents, trade secret protection and CDAs to protect the intellectual property related to our product candidates, proprietary technologies and product candidate development programs. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to our product candidates and proprietary technologies and any future product candidates. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates, and proprietary technology in the United States or in other foreign countries, in whole or in part. Alternately, our existing patents and any future patents it obtains may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. Even if patents do successfully issue, and even if such patents cover our existing product candidates or any future product candidate, third parties may challenge their validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive it of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which it could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our existing product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that it was the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity, patent term or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide it with meaningful protection, prevent competitors from competing with it or otherwise provide it with any competitive advantage.

The patent rights we own covering QTORIN rapamycin are directed to specific methods of use and specific formulations of rapamycin. As a result, our ability to prevent others from marketing products related to QTORIN rapamycin may be limited by the lack of patent protection for the active ingredient itself and other rapamycin formulations may be developed by competitors. No patent protection is available for rapamycin itself, the active ingredient in QTORIN rapamycin. As a result, competitors who develop and receive required regulatory approval for competing products using the same active ingredient as QTORIN rapamycin may market their competing products so long as they do not infringe any of the method or formulation patents owned by us.

Patent terms may be inadequate to protect our competitive position and if it does not obtain additional patent protection by issuing additional patents with longer patent terms for our product candidates, our business may be materially harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from our application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Our issued U.S. patents directed to methods of treating keratin hyperproliferation skin disorders with rapamycin naturally expire as late as 2032. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized.

If we are unable to obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States or may not be pursued at all outside of the United States. For example, We do not own or license any patent rights directed to QTORIN rapamycin outside of the United States Australia, China, Israel and Japan and We do not own or license any patent rights directed to QTORIN with any other mTOR inhibitors outside of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

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. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the "America Invents Act", the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO, during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that it owns, has licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that it owns or has licensed or that we may obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering any of our product candidates, our competitors might be able to enter the market earlier than anticipated, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our product candidates, and it expects to continue to collaborate with third parties on the development of our current and future product candidates, it must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require it to share trade secrets under the terms of collaboration or similar agreements. We seek to protect our proprietary technology in part by entering into CDAs and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom it shares our facilities or third-party consultants and vendors that it engages to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and could materially adversely affect our business, financial condition, results of operations and prospects.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors, outside scientific advisors, licensors or licensees may unintentionally or willfully disclose our information to competitors. We rely, in part, on non-disclosure and CDAs with our employees, consultants and other parties to protect our proprietary information, technology, and know-how. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

We may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that it owns or licenses.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that it owns or licenses or that we may own or license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to it, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that it regards as our own; our licensors may face similar obstacles. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could materially adversely affect our business, financial condition, results of operations and prospects. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against it, delay or prevent the development and commercialization of our current product candidates or any future product candidates.

Our commercial success depends in part on us and our licensors avoiding infringement and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that it infringes or otherwise violates patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, worldwide, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates.

We cannot assure you that our exploitation of QTORIN rapamycin or any future product candidate will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing any of our product candidates, if approved. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

We may be subject to third-party claims in the future against us or our collaborators that would cause it to incur substantial expenses and, if successful against it, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. We may be required to indemnify future collaborators against such claims. If a patent infringement suit were brought against us or our future collaborators, it or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless it obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless it obtained a license or until such patent expires. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights obtained may be nonexclusive, which would not confer a competitive advantage to us from an exclusivity perspective. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms to necessary third-party patent rights. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of these events could materially adversely affect our business, financial condition, results of operations and prospects.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than it can because they have substantially greater resources. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise materially adversely affect our business, financial condition, results of operations and prospects.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our common stock. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common stock. The occurrence of any of these events could materially adversely affect our business, financial condition, results of operations and prospects.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the USPTO, to determine which party is entitled to a patent on the disputed invention. We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings or similar opposition proceedings in the EPO or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that it was the first to file any patent application related to our product candidates.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of us or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that it considers relevant may be incorrect, and our failure to identify and correctly interpret relevant patents, may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. we cannot guarantee that it will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that it no longer infringes the third-party intellectual property rights. Any of these events, even if we was ultimately to prevail, could require it to divert substantial financial and management resources that it would otherwise be able to devote to our business.

We may be subject to claims by third parties asserting that we, our employees or our licensors have misappropriated their intellectual property, including trade secrets, or claiming ownership of what it regards as our own intellectual property.

Many of our employees and our licensor's employees were previously employed at other biotechnology or pharmaceutical companies. Although we and our licensors try to ensure that our employees and our licensor's employees do not use the intellectual property rights, proprietary information or know-how of others in their work for us, including by contract, we or our licensors may be subject to claims that these employees, our licensors or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which could materially adversely affect our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to it, we may in the future be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that it regards as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against it, to determine the ownership of what it regards as our intellectual property.

If we or our licensor fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we and our licensor are successful in prosecuting or defending against such claims, litigation could result in substantial costs.

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

Competitors may infringe, misappropriate or otherwise violate our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims or inform and cooperate with our licensors to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover our technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against it by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. The initiation of a claim against a third party may also cause the third party to bring counterclaims against us such as claims asserting that our patents are invalid or unenforceable.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, obviousness-type double patenting or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable and could result in the revocation, cancelation, amendment or shortening of term of patents we own or license. We cannot be certain that there is no invalidating prior art, of which it and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, We would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. We may find it impractical or undesirable to enforce our intellectual property against some third parties. For instance, we are aware of third parties that have marketed topical rapamycin formulations for the treatment of skin diseases over the internet or through compound pharmacies. These parties do not appear to have regulatory approval, and we have not authorized them in any way to market these products. However, to date we have refrained from seeking to enforce our intellectual property rights against these third parties due to the transient nature of their activities.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities, and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause it to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. In addition, the uncertainties associated with litigation could compromise our ability to compete in the marketplace or to raise the funds necessary to continue our clinical trials and internal research programs, or in-license needed technology or other product candidates. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

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

Additional third parties, apart from our current licensors, may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of these third parties to commercialize our product candidates, in which case it would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed. The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that our in-licenses, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that it licenses, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that it believes are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and
- what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license;
- the effects of termination; and
- the priority of invention of patented technology.

The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates.

We have licensed, or may in the future license, certain intellectual property rights relating to our technology and indications of interest from third parties. If we materially breaches or fails to perform any provision under these license agreements, including failure to make payments to a licensor when due for royalties or milestones and failure to use commercially reasonable efforts to develop and commercialize the licensed technology, such licensors may have the right to terminate our license agreement. If, for any reason, one or more of our agreements with such third parties is terminated or we otherwise loses those rights, it could harm our business. Our license and other agreements impose, and any future collaboration agreements or license agreements it enters into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breaches any such material obligations, or uses the intellectual property licensed to it in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license or otherwise acquire intellectual property rights from us, which could result in it being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which it needs to build name recognition by potential partners or customers in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

We have not yet registered trademarks for a commercial trade name for our lead candidates in the United States or foreign jurisdictions and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for our lead product candidates in the United States or any foreign jurisdiction. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancelation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we proposes to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Furthermore, QTORIN is our proprietary name for our technology platform. Any future commercial tradename for our lead product candidates will be subject to approval by the FDA for commercial use and will not include the QTORIN mark. Accordingly, any goodwill and recognition that we have built for the name in relation to future commercial drug products may be lost.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit it to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates, but that are not covered by the claims of the patents or other intellectual property rights that we own that it has exclusively licensed and has the right to enforce;
- we, our licensors or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that it owns or licenses;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or licenses may not provide it with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where it does not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the U.S. may, under certain circumstances, force us or our licensors to grant a license under our patents to a competitor, thus allowing the competitor to compete with it in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;

- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- we may not develop additional proprietary technologies that are patentable;
- we may not have sufficient time remaining on the term of our patents or the term of our marketing exclusivity to warrant commercialization of our product candidates;
- the patents or intellectual property rights of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and is likely to continue to be volatile and fluctuate substantially.

The trading price of our common stock has been and is likely to continue to be highly volatile. Furthermore, the stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their shares at or above the price they paid for their shares. The market price of our common stock may be influenced by many factors, including:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us, the selling stockholders or other securityholders in the future;
- if we fail to raise an adequate amount of capital to fund its operations or continued development of its product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our product candidates;
- period-to-period fluctuations in our financial results; and
- the other factors described in this "*Risk Factors*" section.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Sales of our common stock or the perception of such sales, by us or the selling stockholders pursuant to this prospectus, in the public market or otherwise, could cause the market price for our securities to decline, even though the selling stockholders would still realize a profit on sales at lower prices. Resales of the securities offered by this prospectus may cause the market price of such securities to drop significantly, even if our business is doing well.

The sale of our common stock in the public market or otherwise, including sales pursuant to this prospectus, or the perception that such sales could occur, could harm the prevailing market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our common stock may cause the market price of our securities to drop significantly, even if our business is doing well.

In addition, the selling stockholders named in this prospectus hold a large portion of our outstanding common stock. The common stock being offered for resale pursuant to this prospectus by the selling stockholders, assuming the full exercise of the Pre-Funded Warrants, would represent approximately 41.16% of our outstanding common stock as of December 20, 2024. Given the substantial number of shares of common stock being registered for potential resale by selling stockholders pursuant to this prospectus, the sale of shares by the selling stockholders of a large number of shares, or the perception in the market that the selling stockholders of a large number of shares intend to sell shares, could increase the volatility of the market price of our common stock or result in a significant decline in the public trading price of our common stock. While certain of the selling stockholders may experience a positive rate of return on their investment in our common stock as a result, the public securityholders may not experience a similar rate of return on the securities they purchased due to differences in their purchase prices and the trading price.

The number of shares being registered for sale is significant in relation to the number of outstanding shares of our common stock. Future sales of shares by existing stockholders could cause our stock price to decline.

As of December 20, 2024, we had approximately 11,221,307 shares of common stock outstanding. This prospectus is a part of a registration statement on Form S-1 that registers up to 5,634,504 shares of common stock for sale into the public market by the selling stockholders. These shares represent a significant number of our outstanding common stock, and if sold in the market all at once or at about the same time, such transactions could depress the market price of our common stock during the period the registration statement remains effective. Any such transaction could also adversely affect our ability to raise equity capital.

In addition, certain of our shares are subject to lock-up agreements. Following the expiration of these lock-up agreements, the relevant stockholders will not be restricted from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock-up agreements will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. In addition, shares of common stock that are subject to outstanding options or will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any legal or contractual restrictions on resale lapse, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of December 20, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 39.85% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to our cash resources.

Because we do not anticipate paying any cash dividends on our share capital in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our shares to provide dividend income. We have never declared or paid cash dividends on our share capital. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements or preferred equity may preclude us from paying dividends. As a result, capital appreciation, if any, of our common shares will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our shares.

Provisions in our charter and bylaws, as well as provisions of Nevada law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our charter and bylaws and Nevada law contain provisions that may have the effect of delaying or preventing a change in control of the Company or changes in our management. Our charter and bylaws, include provisions that:

- authorize “blank check” preferred stock, which could be issued by the Board without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at stockholder meetings;
- prohibit stockholder action by written consent;
- certain limitations on convening special stockholder meetings and the prohibition of stockholder action by written consent; and
- directors may only be removed for cause and only by the affirmative vote of the holders of at least 80% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote at an election of directors, voting together as a single class.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

Any provision of our charter, bylaws or Nevada law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our articles of incorporation contain exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

Our amended and restated articles of incorporation provide that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for any (i) derivative action or proceeding brought in the name or right of the corporation or on our behalf, (ii) action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to the corporation or any of our stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Chapters 78 or 92A of the NRS or any provision of its amended and restated articles of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of its articles of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated articles of incorporation further provide that any person purchasing or otherwise acquiring any interest in shares of its capital stock shall be deemed, to the fullest extent permitted by law, to have notice of and consented to the foregoing provision.

Choice-of-forum provisions of the type and scope included in our amended and restated articles of incorporation are expressly permitted by Section 78.046 of the NRS, but application of these choice-of-forum provisions may be limited in some instances by law. Section 27 of the Exchange Act establishes exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and therefore the choice-of-forum provision would not apply to actions arising under, or brought to enforce a duty or liability created by, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. We note that the choice-of-forum provision does not relieve us of our duty to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived compliance with these laws, rules and regulations.

We believe the choice-of-forum provision in our amended and restated articles of incorporation will help provide for the orderly, efficient and cost-effective resolution of the types of legal issues affecting us, as identified in the choice-of-forum provision, by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents, and could also increase the costs of stockholders in connection with bringing a claim and resolving such matters. If a court were to find the choice-of-forum provision in our amended and restated articles of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

USE OF PROCEEDS

All of the Resale Shares offered by the selling stockholders pursuant to this prospectus will be sold by the selling stockholders for their respective accounts. We will not receive any proceeds from any sales of the Resale Shares by the selling stockholders.

Some of the shares of common stock offered hereby are issuable upon the exercise of the Pre-Funded Warrants. Upon exercise of such Pre-Funded Warrants for cash, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. We intend to use those proceeds, if any, for general corporate purposes.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

Market Information

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "PVLA." Prior to the consummation of the Merger, our common stock was listed on the Nasdaq Capital Market under the symbol "PIRS."

As of December 20, 2024, we had approximately 11,221,307 shares of common stock issued and outstanding held of record by approximately 141 registered holders.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed consolidated combined financial information presents the combination of the financial information of Pieris and Legacy Palvella adjusted to give effect to the Merger, the PIPE Financing and related transactions (collectively, the "Pro Forma Adjustments").

Unless the context indicates otherwise, references in this prospectus to the "Company," "we," "us," "our" and similar terms refer to Palvella Therapeutics, Inc., a Nevada corporation (f/k/a Pieris Pharmaceuticals, Inc.) and its consolidated subsidiaries. References to "Pieris" refer to our predecessor company prior to the Merger. References to "Legacy Palvella" or "Palvella" refer to Palvella Therapeutics, Inc., a Delaware corporation, prior to the Merger and our wholly owned subsidiary upon the consummation of the Merger. Capitalized terms included but not defined below have the same meaning as defined elsewhere in this prospectus.

On December 13, 2024 (the "Closing Date"), Palvella Therapeutics, Inc., a Nevada corporation (the "Company" or "Palvella") (previously named Pieris Pharmaceuticals, Inc. and our predecessor company ("Pieris")), consummated the previously announced merger pursuant to the terms of that certain Agreement and Plan of Merger, dated as of July 23, 2024 (the "Merger Agreement"), by and among the Company, Polo Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Pieris (the "Merger Sub"), and Palvella Therapeutics, Inc., a Delaware corporation ("Legacy Palvella"). Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Palvella, with Legacy Palvella 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 Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc.

In accordance with the terms and subject to the conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger, each outstanding share of Legacy Palvella capital stock (including shares of Legacy Palvella common stock and Legacy Palvella preferred stock) (excluding dissenting shares) was converted into the right to receive a number of shares of Palvella common stock, and (ii) at the effective time of the Merger, the Company issued an aggregate of approximately 6,787,415 shares of its common stock to Legacy Palvella stockholders, based on an exchange ratio of 0.309469242 shares of the Company's common stock for each share of Legacy Palvella capital stock outstanding immediately prior to the Merger, but excluding shares to be canceled pursuant to the Merger Agreement, resulting in approximately 8,316,929 shares of the Company's common stock being issued and outstanding immediately following the effective time of the Merger.

Each stock option granted under the Palvella Stock Plan that was outstanding immediately prior to the effective time of the Merger was assumed by Pieris and became an option to acquire, on the same terms and conditions as were applicable to such Palvella stock option immediately prior to the effective time of the Merger, a number of shares of Pieris common stock equal to the number of shares of Palvella's common stock subject to the unexercised portion of the Palvella stock option immediately prior to the effective time of the Merger, multiplied by the exchange ratio (rounded down to the nearest whole share number) with an exercise price per share for the options equal to the exercise price per share of such Palvella stock option immediately prior to the effective time of the Merger divided by the exchange ratio (rounded up to the nearest whole cent). Such assumed options continue to be governed by the terms and conditions of the Palvella Stock Plan.

All outstanding Pieris stock options were canceled prior to the Merger for no consideration due to these awards being out of money. This decision aligned with Pieris' stock compensation plan and reflected the financial strategy to streamline equity compensation amidst ongoing developments and collaborations.

The pre-Merger employment agreements for the two Pieris executives also included severance, bonus and retention payments, the aggregate of which will be treated as pre-combination compensation expense of Pieris and is included in the liabilities assumed by Palvella upon closing of the Merger. In addition, certain non-executive Pieris employees entered into separation agreements prior to Merger negotiations with Palvella, pursuant to which they are entitled to severance, bonus, and retention payments. These payments will be treated as pre-combination compensation expense of Pieris and will also be included in the liabilities assumed by Palvella upon closing of the Merger.

Contingent Value Rights Agreement

Prior to the effective time of the Merger, Pieris entered into a CVR Agreement with a rights agent (the "Rights Agent") and a CVR holder representative, pursuant to which each holder of record of shares of Pieris' common stock and preferred stock entitled to receive a dividend in accordance with the terms of such preferred stock received the right to one contingent value right (each, a "CVR") for each outstanding share of Pieris' common stock held by such stockholder, or share of common stock underlying such preferred stock, held by such stockholder, on such date. Each CVR represents the contractual right to receive payments upon the receipt of payments by Pieris or any of its affiliates under certain strategic partner agreements, including existing collaboration agreements pursuant to which Pieris may be entitled to milestones and royalties in the future and other outlicensing agreements for certain of Pieris' legacy assets, and upon the receipt of certain research and development tax credits in favor of Pieris or any of its affiliates, in each case as set forth in, and subject to and in accordance with the terms and conditions of, the CVR Agreement.

Management concluded that the CVRs meet the definition of a derivative and will be initially measured at the aggregate estimated fair value of the CVRs and will be subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in fair value of the CVR derivative are presented in the consolidated statements of operations and comprehensive income (loss). The derivative value is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, and risk-adjustment discount rates, which represent a Level 3 measurement within the fair value hierarchy. Management has concluded that there is no value associated with the CVRs as the likelihood of any payments received in connection with Pieris' legacy assets is remote.

Palvella Private Financing and PIPE Financing

On June 6, 2024, Palvella initiated a sequence of convertible notes with certain investors via the Convertible Note Purchase Agreement (the "Note Purchase Agreement"). Under the Note Purchase Agreement, the investors committed to extend credit to Palvella, providing up to a total of $20 million (the "Authorized Principal Amount") via convertible promissory notes. Prior to the Merger, Palvella received $18.4 million of gross proceeds in exchange for convertible promissory notes issued. The convertible note bears an annual interest of 2.0% plus SOFR and was due and payable upon the earlier to occur of June 2027 or certain events defined in the Note Purchase Agreement. Under certain circumstances, the convertible note was convertible at the option of requisite holders into equity securities at defined conversion prices. The terms of the convertible note provided that upon the consummation of the Merger, all outstanding principal and any unpaid accrued interest on the notes shall be automatically converted into common stock.

Concurrently with the execution of the Merger Agreement on July 23, 2024, Pieris entered into a securities purchase agreement (the "Purchase Agreement") with the selling stockholders identified in this prospectus, pursuant to which, among other things, on the Closing Date and immediately following the consummation of the Merger, the selling stockholders purchased (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Legacy Palvella), and the Company issued and sold to the PIPE Investors, an aggregate of 3,168,048 shares of the Company's common stock at a price per share equal to $13.9965 (the "Purchase Price"), and/or in lieu of the Company's common stock to certain purchasers who so choose due to beneficial ownership concerns, pre-funded warrants (the "Pre-Funded Warrants") to purchase 2,466,456 shares of the Company's common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price minus $0.001 (the "PIPE Financing"). The gross proceeds from the PIPE Financing were approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest payable under the outstanding convertible notes issued by Legacy Palvella, before paying estimated expenses. The closing of the PIPE Financing occurred on December 13, 2024, immediately following the consummation of the Merger.

The Merger is expected to be accounted for as a reverse recapitalization in accordance with US GAAP. Under this method of accounting, Pieris, which is the legal acquirer, is treated as the "acquired" company for financial reporting purposes and Palvella is treated as the accounting acquirer. This determination was primarily due to Pieris being determined to be a shell company in that it did not meet the US GAAP definition of a business, did not have more than nominal assets, and does not have more than nominal operations at the time of the merger. Further, immediately following the Merger, Palvella's stockholders had a majority of the voting power of the combined company, Palvella controls five of six seats on the board of directors of the combined company, and Palvella's senior management will comprise all of the senior management of the combined company. Accordingly, for accounting purposes, the Merger will be treated as the equivalent of a capital transaction in which Palvella is issuing stock for the net assets of Pieris. The net assets of Pieris will be stated at historical cost, with no goodwill or other intangible assets recorded.

The following unaudited pro forma condensed consolidated combined balance sheet as of September 30, 2024 combines the historical condensed consolidated balance sheet of Pieris as of September 30, 2024 with the historical balance sheet of Palvella as of September 30, 2024 giving further effect to the Pro Forma Adjustments, as if they had been consummated as of September 30, 2024.

The following unaudited pro forma condensed consolidated combined statements of operations for the year ended December 31, 2023 combine the historical condensed consolidated statement of operations of Pieris for the year ended December 31, 2023 and the historical statements of operations of Palvella for the year ended December 31, 2023, giving effect to the Pro Forma Adjustments as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The following unaudited pro forma condensed consolidated combined statements of operations for the nine months ended September 30, 2024 combine the historical condensed consolidated statement of operations of Pieris for the nine months ended September 30, 2024 and the historical statements of operations of Palvella for the nine months ended September 30, 2024, giving effect to the Pro Forma Adjustments as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The unaudited pro forma condensed consolidated combined financial statements have been derived from and should be read in connection with:

- the accompanying notes to the unaudited pro forma condensed consolidated combined financial statements;
- the historical unaudited condensed consolidated financial statements of Pieris as of and for the nine months ended September 30, 2024 and the related notes included elsewhere in this prospectus;
- the historical unaudited condensed financial statements of Palvella as of and for the nine months ended September 30, 2024 and the related notes included elsewhere in this prospectus;
- the historical audited consolidated financial statements of Pieris as of and for the year ended December 31, 2023 and the related notes included elsewhere in this prospectus;
- the historical audited financial statements of Palvella as of and for the year ended December 31, 2023 and the related notes included elsewhere in this prospectus;
- the sections entitled “Pieris Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Palvella Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and other financial information relating to Pieris and Palvella included elsewhere in this prospectus.

The unaudited pro forma condensed consolidated combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The accounting for the Merger requires the financial calculation of Pieris’ net cash. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma condensed consolidated combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed consolidated combined financial information and the combined company’s future results of operations and financial position.

The unaudited pro forma condensed combined consolidated financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed consolidated combined financial information is not necessarily indicative of the financial position or results of operations in the future periods or the result that actually would have been realized had Pieris and Palvella been a combined organization during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited condensed consolidated combined pro forma financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma condensed consolidated combined financial information.

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED BALANCE SHEET AS OF SEPTEMBER 30, 2024
(in thousands)

	Historical						
	Palvella	Pieris	Private Financing Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Asset							
Current assets:							
Cash and cash equivalents	$ 14,207	$ 19,363	$ 6,000	(a)	$ 53,501	(b) (f)	$ 93,071
Accounts receivable	-	373	-		-		373
Other receivables	-	506	-		-		506
Deferred transaction costs	1,673	-	-		(1,673)	(f)	-
Prepaid expenses and other current assets	441	280	-		-		721
Total Current Assets	16,321	20,522	6,000		51,828		94,671
Total assets	$ 16,321	$ 20,522	$ 6,000		$ 51,828		$ 94,671
Liabilities, convertible preferred stock and stockholders' equity (deficit)							
Current liabilities:							
Accounts Payable	$ 3,130	$ 801	$ -		$ -		$ 3,931
Accrued expenses and other current liabilities	4,505	3,453	-		(1,124)	(c) (f)	6,834
Total Current Liabilities	7,635	4,254	-		(1,124)		10,765
Royalty agreement liability	10,819	-	-		-		10,819
Derivative liabilities – royalty agreement	1,418	-	-		-		1,418
Convertible promissory notes	13,250	-	6,000	(a)	(19,250)	(d)	-
Total liabilities	33,122	4,254	6,000		(20,374)		23,002
Palvella convertible preferred stock	70,603	-	-		(70,603)	(e)	-
Pieris convertible preferred stock	-	-	-		-		-
Stockholders' equity (deficit):							
Palvella common stock, $0.00001 par value	-	-	-		-		-
Pieris common stock	-	1	-		13	(b) (d) (e)	14
Additional paid-in capital	2,380	342,916	-		(183,057)	(b) (d) (e) (f) (g) (h)	162,239
Accumulated other comprehensive (loss) income	-	(316)	-		316	(g)	-
Accumulated deficit	(89,784)	(326,333)	-		325,533	(c) (f) (h)	(90,584)
Total stockholders' equity (deficit)	(16,801)	16,268	-		72,202		71,669
Total liabilities, convertible preferred stock and stockholders' equity	$ 16,321	$ 20,522	$ -		$ 51,828		$ 94,671

See accompanying notes to the unaudited pro forma condensed combined financial statements

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED STATEMENT OF OPERATIONS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024
(in thousands, except share and per share data)

	Historical						
	Palvella	Pieris	Private Financing Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Revenue:							
Customer revenue	$ -	$ 6	$ -		$ -		$ 6
Collaboration revenue	-	47	-		-		47
Total revenue	-	53	-		-		53
Operating expenses:							
Research and development	5,608	1,523	-		-		7,131
General and administrative	4,121	11,145	-		-		15,266
Total operating expenses	9,729	12,668	-		-		22,397
Operating loss	(9,729)	(12,615)	-		-		(22,344)
Other income (expense), net:							
Interest income (expense)	(2,764)	610	-		-		(2,154)
Interest income (expense) – convertible notes payable	(249)	-	-		249	(i)	-
Fair value adjustments on derivative liabilities	(404)	-	-		-		(404)
Fair value adjustments on convertible notes payable	(568)	-	-		568	(j)	-
Other income (loss)	231	636	-		-		867
Total other income (expense), net	(3,754)	1,246	-		817		(1,691)
Net Income (loss)	$ (13,483)	$ (11,369)	$ -		$ 817		$ (24,035)
Net profit (loss) per share							
Basic	$ (2.46)	$ (8.84)					$ (1.76)
Diluted	$ (2.46)	$ (8.84)					$ (1.76)
Weighted average number of common shares outstanding							
Basic	5,720,009	1,285,000				(k)	13,652,523
Diluted	5,720,009	1,285,000				(k)	13,652,523

See accompanying notes to the unaudited pro forma condensed combined financial statements

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2023
(in thousands, except share and per share data)

	Historical						
	Palvella	Pieris	Private Financing Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Revenue:							
Customer revenue	$ -	$ 38,711	$ -		$ -		$ 38,711
Collaboration revenue	-	4,099	-		-		4,099
Total revenue	-	42,810	-		-		42,810
Operating expenses:							
Research and development	8,793	41,801	-		-		50,594
General and administrative	3,076	16,853	-		800	(f)	20,729
Asset impairment	-	13,912	-		-		13,912
Total operating expenses	11,869	72,566	-		800		85,235
Operating loss	(11,869)	(29,756)	-		-		(42,425)
Other income (expense), net:							
Interest income (expense)	6,265	1,851	-		-		8,116
Grant income	-	3,612	-		-		3,612
Gain on extinguishment – royalty agreement	23,098	-			-		23,098
Fair value adjustments on derivative liabilities	485	-	-		-		485
Other income (loss)	712	(250)	-		-		462
Total other income (expense), net	30,560	5,213	-		-		35,773
Net Income (loss)	$ 18,691	$ (24,543)	$ -		$ 800		$ (6,652)
Net profit (loss) per share							
Basic	$ 0.68	$ (21.80)					$ (0.49)
Diluted	$ 0.67	$ (21.80)					$ (0.49)
Weighted average number of common shares outstanding							
Basic	5,720,009	1,125,800				(k)	13,576,875
Diluted	5,796,956	1,125,800				(k)	13,576,875

See accompanying notes to the unaudited pro forma condensed combined financial statements

NOTES TO THE UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED FINANCIAL INFORMATION

1. Description of the Transactions

The Merger

On the Closing Date, the Company consummated the previously announced Merger pursuant to the terms of the Merger Agreement, dated July 23, 2024. Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Palvella, with Palvella continuing as the wholly owned subsidiary of the Company and (ii) the Company's name was changed from Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc. Upon the Closing, the business of Palvella continued as the business of the combined company. The Merger was intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended. Post Merger, the business of Palvella will continue as the business of the combined Company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each outstanding share of Palvella capital stock (including shares of Palvella common stock and Palvella preferred stock) (excluding dissenting shares) was converted solely into the right to receive a number of shares of Pieris common stock calculated in accordance with the Merger Agreement, equal to the exchange ratio calculated in accordance with the Merger Agreement. Based on Pieris' and Palvella's capitalization as of December 13, 2024, the exchange ratio was 0.309469242 shares of Pieris common stock for each share of Palvella capital stock. Immediately after the Merger, but without giving effect to the PIPE Financing, Pieris securityholders as of immediately prior to the Merger owned approximately 18.4% of the outstanding shares of capital stock of the combined company and Palvella securityholders as of immediately prior to the Merger owned approximately 81.6% of the outstanding shares of capital stock of the combined Company, in each case, on a fully-diluted basis, calculated using the treasury stock method, and subject to certain assumptions, including, a valuation for Pieris equal to $21.4 million.

Each stock option granted under the Palvella Stock Plan that was outstanding immediately prior to the effective time of the Merger was assumed by Pieris and became an option to acquire, on the same terms and conditions as were applicable to such Palvella stock option immediately prior to the effective time of the Merger, a number of shares of Pieris common stock equal to the number of shares of Palvella's common stock subject to the unexercised portion of the Palvella stock option immediately prior to the effective time of the Merger, multiplied by the exchange ratio (rounded down to the nearest whole share number) with an exercise price per share for the options equal to the exercise price per share of such Palvella stock option immediately prior to the effective time of the Merger divided by the exchange ratio (rounded up to the nearest whole cent). Such assumed options continue to be governed by the terms and conditions of the Palvella Stock Plan.

All outstanding Pieris stock options were canceled prior to the Merger for no consideration due to these awards being out of money. This decision aligns with Pieris' current stock compensation plan and reflects the financial strategy to streamline equity compensation amidst ongoing developments and collaborations.

The pre-Merger employment agreements for the two Pieris executives also included severance, bonus and retention payments, the aggregate of which will be treated as pre-combination compensation expense of Pieris and is included in the liabilities assumed by Palvella upon closing of the Merger. In addition, certain non-executive Pieris employees entered into separation agreements prior to Merger negotiations with Palvella, pursuant to which they are entitled to severance, bonus, and retention payments. These payments will be treated as pre-combination compensation expense of Pieris and will also be included in the liabilities assumed by Palvella upon closing of the Merger.

Contingent Value Rights Agreement

Prior to the effective time of the Merger, Pieris entered into a CVR Agreement with a rights agent (the "Rights Agent") and a CVR holder representative, pursuant to which each holder of record of shares of Pieris' common stock and preferred stock entitled to receive a dividend in accordance with the terms of such preferred stock received the right to one contingent value right (each, a "CVR") for each outstanding share of Pieris' common stock held by such stockholder, or share of common stock underlying such preferred stock, held by such stockholder, on such date. Each CVR represents the contractual right to receive payments upon the receipt of payments by Pieris or any of its affiliates under certain strategic partner agreements, including existing collaboration agreements pursuant to which Pieris may be entitled to milestones and royalties in the future and other outlicensing agreements for certain of Pieris' legacy assets, and upon the receipt of certain research and development tax credits in favor of Pieris or any of its affiliates, in each case as set forth in, and subject to and in accordance with the terms and conditions of, the CVR Agreement.

Management concluded that the CVRs meet the definition of a derivative and will be initially measured at the aggregate estimated fair value of the CVRs and will be subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in fair value of the CVR derivative are presented in the consolidated statements of operations and comprehensive income (loss). The derivative value is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, and risk-adjustment discount rates, which represent a Level 3 measurement within the fair value hierarchy. Management has concluded that there is no value associated with the CVRs as the likelihood of any payments received in connection with Pieris' legacy assets is remote.

Palvella Private Financing and PIPE Financing

On June 6, 2024, Palvella initiated a sequence of convertible notes with certain investors via a Convertible Note Purchase Agreement (the "Note Purchase Agreement"). Under the Note Purchase Agreement, the investors committed to extend credit to Palvella, providing up to a total of $20 million (the "Authorized Principal Amount") via convertible promissory notes. Through the issuance date of this filing, Palvella received $18.4 million of gross proceeds in exchange for convertible promissory notes issued. The convertible note included annual interest of 2.0% plus SOFR and were due and payable upon the earlier to occur of June 2027 or certain events defined in the Note Purchase Agreement. Under certain circumstances, the convertible note was convertible at the option of requisite holders into equity securities at defined conversion prices. The terms of the convertible note specified that upon the consummation of the Merger, all outstanding principal and any unpaid accrued interest on the notes were automatically converted into common stock of the combined Company.

Concurrently with the execution of the Merger Agreement on July 23, 2024, Pieris entered into the Purchase Agreement with the PIPE Investors, pursuant to which, among other things, on the Closing Date and immediately following the consummation of the Merger, the PIPE Investors purchased (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Palvella), and the Company issued and sold to the selling stockholders, an aggregate of 3,168,048 shares of the Company's common stock at a price per share equal to $13.9965, and/or in lieu of the Company's common stock to certain purchasers who so choose due to beneficial ownership concerns, the Pre-Funded Warrants to purchase 2,466,456 shares of the Company's common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price minus $0.001. The gross proceeds from the PIPE Financing were approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest payable under the outstanding convertible notes issued by Palvella, before paying estimated expenses. The closing of the PIPE Financing occurred on December 13, 2024, immediately following the consummation of the Merger.

The Merger is expected to be accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, Pieris, which is the legal acquirer, is treated as the "acquired" company for financial reporting purposes and Palvella is treated as the accounting acquirer. This determination was primarily due to Pieris being determined to be a shell company in that it did not meet the GAAP definition of a business, did not have more than nominal assets, and does not have more than nominal operations at the time of the Merger. Further, immediately following the Merger, Palvella's stockholders had a majority of the voting power of the combined Company, Palvella controlled five of six seats on the board of directors of the combined Company, and Palvella's senior management comprised all of the senior management of the combined company. Accordingly, for accounting purposes, the Merger will be treated as the equivalent of a capital transaction in which Palvella is issuing stock for the net assets of Pieris. The net assets of Pieris will be stated at historical cost, with no goodwill or other intangible assets recorded.

2. Basis of Pro Forma Presentation

The unaudited pro forma condensed consolidated combined financial information was prepared pursuant to the rules and regulations of Article 11 of Regulation S-X. The unaudited pro forma condensed consolidated combined balance sheet as of September 30, 2024 was prepared using the historical balance sheets of Pieris and Palvella as of September 30, 2024, and gives effect to the Merger and the PIPE Financing as if they occurred on September 30, 2024. The unaudited pro forma condensed consolidated combined statement of operations for the nine months ended September 30, 2024, and for the year ended December 31, 2023, were prepared using the historical statements of operations of Pieris and Palvella for the nine months ended September 30, 2024 and for the year ended December 31, 2023, respectively, and gives effect to the Merger and the PIPE Financing as if they occurred on January 1, 2023.

The Merger is expected to be accounted for as a reverse recapitalization in accordance with GAAP, which is the equivalent of a capital transaction in which Palvella has issued stock for the net assets of Pieris. As the operations of Pieris were in the process of being wound down leading up to the date of the Merger, the net assets of Pieris were nominal as of the date of the Merger, resulting in Pieris being a public shell company. As a result of the Merger, the net assets of Pieris will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Merger are of Palvella.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. During preparation of the unaudited pro forma condensed consolidated combined financial information, management performed a preliminary analysis and was not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the Merger and the PIPE Financing, management is in the process of conducting a final review of Pieris accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Pieris results of operations or reclassification of assets or liabilities to conform to Palvella's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on this unaudited pro forma condensed consolidated combined financial information.

Palvella and Pieris may incur significant costs associated with integrating their operations as a result of the Merger. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies, which may result from the Merger.

To the extent that there are significant changes to the business as a result of the Merger, the assumptions and estimates set forth in the unaudited pro forma condensed consolidated financial information could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the completion of the Merger. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

3. Shares of Pieris Common Stock Issued to Palvella's Stockholders Upon Closing of the Merger

At the effective time of the Merger, Pieris issued 6,650,532 shares of common stock to the stockholders of Palvella in the Merger, determined as follows:

	Shares
Palvella shares of common stock outstanding	5,720,009
Shares of Palvella convertible preferred stock outstanding	15,360,787
Total Palvella common stock equivalent shares	21,080,796
Exchange ratio	0.309469242
Estimated shares of Pieris common stock to be issued to Palvella stockholders upon closing of the Merger	6,523,750

4. Pro Forma Adjustments

Adjustments included in the column under the heading "Transaction Accounting Adjustments" are primarily based on information contained within the Merger Agreement, the Note Purchase Agreement, and the PIPE. Adjustments included in the column under the heading "Private Financing Adjustments" are primarily based on information contained in the Note Purchase Agreement and the PIPE. Further analysis will be performed upon completion of the Merger to confirm these estimates.

Based on a review of Pieris' summary of significant accounting policies, the nature and amount of any adjustments to the historical consolidated financial statements of Pieris to conform to the accounting policies of Palvella are not expected to be significant.

Both Palvella and Pieris had a history of generating net operating losses and maintaining a full valuation allowance against their net deferred tax assets. As a result, both entities have not reflected an income tax benefit or expense within the historical financial statement periods presented. Management has not identified any changes to the income tax positions due to the Merger that would result in an incremental tax expense or benefit. Accordingly, no tax-related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

(a) To reflect $18.4 million in gross proceeds received pursuant to the Note Purchase Agreement as of the date of this filing, with $12.4 million of the proceeds already accounted for on Palvella's historical balance sheet as of September 30, 2024.

(b) To reflect the $60.0 million received in connection with the PIPE, for which approximately 4.3 million shares of Pieris common stock were issued upon closing of the Merger, offset by $6.5 million in transaction costs incurred.

(c) To reflect Pieris' estimated compensation expense of $0.5 million related to severance, retention, and bonus payments that were negotiated pre-Merger but had not yet been paid or fully accrued for as of September 30, 2024. As such, the $0.5 million is recorded as an assumed liability within the unaudited combined pro forma balance sheet as of September 30, 2024, and offset to accumulated deficit. As it is considered a preacquisition expense, there is no related adjustment within the unaudited condensed consolidated combined pro forma statements of operations. This amount is offset by the payment at the closing of the merger of $1.7 million in transaction costs accrued as of September 30, 2024.

(d) To reflect the conversion of the $18.4 million issued under the Note Purchase Agreement, plus accrued interest for a total of $18.9 million to 1.3 million shares of Pieries common stock upon closing of the Merger.

(e) To reflect the exchange of 15,360,787 shares of Palvella convertible preferred stock into shares of Palvella common stock, which, together with the 5,720,009 shares of outstanding Palvella common stock, were then converted in aggregate into 6,523,750 shares of Pieris common stock based on the exchange ratio.

(f) To reflect Palvella's preliminary estimated transaction costs of $6.5 million in connection with the Merger, such as advisor fees, legal fees, printer fees, and accounting expenses, of which $1.7 million of the transaction costs already accrued and deferred on Palvella's historical balance sheet as of September 30, 2024. These transaction costs that are directly attributable to the transaction are recorded as an offset to additional paid-in capital. Based on the estimates of management, of the $6.5 million of transaction costs incurred, $5.7 million was offset against additional paid-in capital and $0.8 million was recorded to general and administrative expense in the unaudited condensed consolidated combined pro forma statement of operations.

(g) To reflect the reclassification of Pieris accumulated other comprehensive income (loss) into additional paid-in capital.

(h) To reflect the reclassification of historical accumulated deficit of Pieris into additional paid-in capital.

(i) To reflect the reversal of interest expense accrued on the convertible notes during the period ended September 30, 2024 that were converted upon closing of the Merger to shares of Pieris common stock upon closing of the Merger.

(j) To reflect the reversal of change in fair value of the convertible notes during the period ended September 30, 2024 that were converted upon closing of the Merger to share of Pieris common stock upon closing of the merger.

(k) The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net income (loss) for the nine months ended September 30, 2024, and the year ended December 31, 2023. In addition, the number of shares used to calculate the pro forma combined basic and diluted net income (loss) per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the Merger closing date, including the shares to be issued in the PIPE Financing, as if they have been outstanding for the entirety of the periods presented. For the nine months ended September 30, 2024, and the year ended December 31, 2023, the pro forma weighted average shares outstanding has been calculated as follows:

	September 30, 2024	December 31, 2023
Weighted-average Palvella common shares outstanding – basic and diluted	5,720,009	5,720,009
Palvella convertible preferred stock	15,360,787	15,360,787
Total	21,080,796	21,080,796
Application of exchange ratio	0.309469	0.309469
Adjusted Weighted-average Palvella common shares outstanding – basic and diluted	6,523,750	6,523,750
$18.9 million of Palvella convertible notes	1,347,666	1,347,666
$60.0 million of PIPE Financing	4,286,838	4,286,838
Weighted-average Pieris common shares outstanding	1,285,000	1,125,800
Pieris convertible preferred stock	208,331	208,331
Pieris reverse stock split adjustment	-	83,552
Pieris planned issuance of common shares	938	938
Pro forma combined weighted average number of shares of common stock – basic and diluted	13,652,523	13,576,875

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited interim consolidated financial statements and the related notes thereto as of September 30, 2024, and for the three and nine months ended September 30, 2024 and 2023, included elsewhere in this prospectus and our audited consolidated financial statements as of and for the fiscal year ended December 31, 2023 and the related notes appearing elsewhere or incorporated by reference in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this prospectus.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "the Company," "we," "us," and "our" refer to the business and operations of Palvella Therapeutics, Inc., a Delaware corporation (referred to as "Legacy Palvella") prior to the Merger, and the business and operations of Palvella Therapeutics, Inc., a Nevada Corporation (previously Pieris Pharmaceuticals, Inc., referred to as "Pieris") and its consolidated subsidiaries following the Merger.

Overview

We are a clinical-stage biopharmaceutical company whose vision is to become the leading rare disease biopharmaceutical company focused on developing and, if approved, commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no FDA-approved therapies. We intend to leverage our versatile QTORIN platform to treat these patients. QTORIN is designed to generate new therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of rare genetic skin diseases. Our lead product candidate, QTORIN rapamycin, is in clinical development for two of these diseases: microcystic lymphatic malformations (LM), and cutaneous venous malformations. QTORIN rapamycin contains the active pharmaceutical ingredient rapamycin, also known as sirolimus, which is an inhibitor of mTOR, a kinase that plays a key role in cell growth and proliferation.

We currently have one ongoing clinical trial and one clinical trial planned to start in the fourth quarter of 2024. Our ongoing trial, SELVA, is a Phase 3 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin in the Treatment of Microcystic LM. We previously announced topline Phase 2 clinical trial results from the multi-center, open-label study of 12 subjects receiving QTORIN™ rapamycin once-daily for 12-weeks. The Phase 2 clinical trial featured multiple pre-specified efficacy assessments, including clinician and patient global impression assessments as well as assessments of individual clinical manifestations that are important disease burdens for individuals living with microcystic LMs. All participants in the Phase 2 clinical trial demonstrated improvements on the Clinician Global Impression of Change scale, with all participants in the study rated as either "Much Improved" (n=7, 58%) or "Very Much Improved" (n=5, 42%) after 12-weeks of treatment compared to the pre-treatment baseline period. We expect to report top-line data for the Phase 3 study in approximately 40 participants with microcystic LM in the first quarter of 2026.

Microcystic LM is a serious, chronically debilitating, and lifelong disease of the lymphatic system characterized by lymphorrhea and acute cellulitis. It is estimated that there are more than 30,000 diagnosed patients in the United States with microcystic LM. The specific pathophysiology of microcystic LM is primarily the result of somatic activating mutations in PIK3CA which result in increased activation of the PI3K/mTOR pathway and subsequent lymphatic hyperplasia. Because microcystic LM has a well-understood pathophysiology and has a well-defined disease course, we believe the optimal clinical study for this rare disease is a baseline-controlled Phase 3 study that incorporates both live clinician assessments and review by a blinded committee.

We have received Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation from the FDA for QTORIN rapamycin for the treatment of microcystic LM. We have also received Fast Track Designation from the FDA for the treatment of venous malformations.

There are no FDA-approved therapies currently indicated for either microcystic LM or cutaneous venous malformations. If approved for the treatment of microcystic LM or cutaneous venous malformations, we believe QTORIN rapamycin has the potential to become the standard of care for these diseases.

We also have a planned study for cutaneous venous malformations, a Phase 2 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin for the Treatment of Cutaneous Venous Malformations expected to start in the fourth quarter of 2024. Cutaneous venous malformations are a serious disease with a high unmet need characterized by dysregulated growth of malformed veins impacting the skin, causing functional impairment and deformity. It is estimated that there are more than 75,000 diagnosed patients in the United States with cutaneous venous malformations. We are conducting a Phase 2 baseline-controlled clinical trial in approximately 15 participants in this patient population and expect to report top-line data in the fourth quarter of 2025.

We also have additional preclinical research programs based on our QTORIN platform for the treatment of serious, rare genetic skin diseases for which we believe there are significant unmet needs. As we plan to expand our pipeline into new rare skin diseases, we plan to generate new product candidates with our QTORIN platform.

We have multiple patents and patent applications directed to anhydrous gel formulations of rapamycin, including QTORIN rapamycin, and the use of such anhydrous gel formulations for the treatment certain skin disorders, including microcystic LM and venous malformations. Our issued U.S. patents with claims directed to certain anhydrous gel formulations containing rapamycin and methods of treatment expire as in 2038.

Background

Legacy Palvella was formed under the laws of the State of Delaware on September 11, 2015 as Palvella Therapeutics LLC, a limited liability company. On May 30, 2018, Legacy Palvella converted into a Delaware corporation and changed its name to Palvella Therapeutics, Inc. Since Legacy Palvella's inception, it has devoted substantially all of its time to identifying, researching and conducting preclinical and clinical activities for its product candidates, acquiring and developing its platform technology, organizing and staffing its company, business planning, raising capital and establishing its intellectual property portfolio.

Since Legacy Palvella's inception in 2015, it has incurred significant operating losses, and Legacy Palvella never generated any revenue. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and commercialization of QTORIN rapamycin and other future product candidates. Further, if Legacy Palvella enters into license or collaboration agreements for any of its product candidates or intellectual property, Legacy Palvella may generate revenue in the future from payments as a result of such license or collaboration agreements; however, there can be no assurance that Legacy Palvella will be able to enter into any license or collaboration agreements. Legacy Palvella's operating loss was $5.1 million and $1.5 million and $9.7 million and $10.4 million for the three and nine months ended September 30, 2024 and 2023, respectively, and $11.9 million and $18.0 million for the years ended December 31, 2023 and 2022, respectively. Since inception, Legacy Palvella's operations have been financed primarily by aggregate net proceeds of $76.5 million from the issuance of convertible preferred stock and convertible notes and $15.0 million from the Ligand Agreements with Ligand which is discussed further below. As of December 31, 2023, Legacy Palvella had an accumulated deficit of $76.3 million and cash and cash equivalents of $7.4 million. As of September 30, 2024, Legacy Palvella had an accumulated deficit of $89.8 million and cash equivalents of $14.2 million.

We expect to continue to incur significant operating losses for the foreseeable future and expect to incur increased expenses as we continue to advance our product candidates through clinical trials and regulatory submissions. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the closing of the Merger (see the section below entitled "*Merger*"), we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that Legacy Palvella did not incur as a private company. If we receive regulatory approval for QTORIN rapamycin for treatment of Microcystic LM, venous malformations or any future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Our losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Ligand Development Funding and Royalty Agreement

In December 2018, Legacy Palvella entered into the Original Ligand Agreement, whereby Ligand made a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. In November 2023, pursuant to the Amended Ligand Agreement, Ligand made an additional one-time payment of $5.0 million to fund the development of QTORIN rapamycin. Under the Amended Ligand Agreement, Ligand is entitled to receive up to $8.0 million in milestone payments upon the achievement of certain milestones by us related to QTORIN rapamycin for the treatment of any and all indications, of which $5.0 million of potential future milestone payments remain under the arrangement. In addition, we agreed to pay to Ligand tiered royalties from 8.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. The Amended Ligand Agreement includes an option for Ligand to purchase additional product revenue participation rights from us over a certain period of time (as set forth in the Amended Ligand Agreement). The option allows Ligand, for each product developed on the QTORIN platform that completes the first human clinical trial in the United States, the opportunity to make an upfront payment (as set forth in the Amended Ligand Agreement) to us in return for a royalty rate (as set forth in the Amended Ligand Agreement). Our obligation to make future milestone payments under the Amended Ligand Agreement was determined to be a derivative liability and our obligation to make future royalty payments was determined to be a debt instrument. Please see "*—Critical Accounting Policies and Significant Judgments and Estimates—Ligand Agreement*" and "*Business—Ligand Development Funding Agreement.*"

Recent Developments

Merger

On July 23, 2024, Legacy Palvella entered into the Merger Agreement with Pieris and the Merger closed on December 13, 2024.

PIPE Financing

On July 23, 2024, Pieris entered into the Purchase Agreement with the certain investors, including BVF Partners, L.P., an existing stockholder of Pieris (the "PIPE Investors"). The PIPE Financing closed on December 13, 2024. The gross proceeds from the PIPE Financing were approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest payable under the outstanding convertible notes issued by Legacy Palvella, before paying estimated expenses.

Impact of Global Economic Events

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including increases in inflation and geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, and supply chain disruptions. While our management is closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on its participants in its Phase 3 clinical trials, employees, suppliers, vendors and business partners, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside our control and could exist for an extended period of time. Management will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources. For additional information, see the section entitled "*Risk Factors—Risks Related to Palvella.*"

Components of Operating Results

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of its product candidates, which include:

- costs related to production of preclinical and clinical materials, including CMC fees paid to CMOs;
- personnel costs, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- vendor expenses related to the execution of preclinical studies and clinical trials;
- expenses incurred under agreements with consultants that conduct research and development activities on our behalf;
- costs related to compliance with regulatory requirements; and
- allocated overhead, including rent, equipment and information technology costs.

We expense all research and development expenses in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and other service providers. This process involves reviewing open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our indirect research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs to identify and develop product candidates.

Research and development activities account for a significant portion of our operating expenses. we expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in advancing our programs and conducting clinical trials. In particular, we expect to incur substantial research and development expenses to continue late-stage clinical development and pursue regulatory approvals of QTORIN rapamycin for the treatment of microcystic LM, venous malformations and the development of our preclinical programs. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than it currently anticipate and may depend substantially upon the performance of certain third-party contractors;

- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any, or experienced by competitors who are developing topical rapamycin products or who are targeting the same indications in the rare genetic skin diseases space;
- the ability of CMOs upon which we rely to manufacture clinical supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to retain patients who have enrolled in a clinical study but may be prone to withdraw due to the rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest;
- our ability to establish and enforce intellectual property rights in and to our current product candidates or any future product candidates; and
- minimizing and managing any delay or disruption to our ongoing or planned clinical trials.

A change in the outcome of any of these factors with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

We may never succeed in achieving regulatory approval for any of our product candidates. Our preclinical studies and clinical trials may be unsuccessful. We may elect to discontinue, suspend or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct additional clinical trials beyond those that we currently anticipate will be required for the completion of any of our product candidates' clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development for such product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of the following costs:

- personnel costs, including salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions; and
- professional fees for legal, intellectual property, information technology, financial, human resources, consulting, audit and accounting services not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase substantially in the future as we increase our headcount to support our organizational growth. Following the completion of the Merger, we also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with our operations as a public company. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing organization to support product sales, marketing and distribution activities.

Other (Expense) Income

Our other (expense) income for the years ended December 31, 2023 and 2022 primarily consists of non-cash interest expense with respect to the royalty agreement liability, and fair value adjustments on the derivative liability components of the Ligand Agreements. Our other (expense) income is subject to variability due to changes in the fair value of the derivative liabilities as well as the potential variability of the royalty agreement liability, both of which are based on significant estimates regarding the timing and success of future development and commercialization activities. During the second quarter of 2023, we received data from certain of our clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization, resulting in a significant reduction in the expected future royalty payments and a corresponding reduction in the royalty agreement liability. In November 2023, the Ligand Agreement was extinguished and the Amended Ligand Agreement was recorded at the estimated fair value of the royalty agreement liability on the date of the amendment. This resulted in a non-cash gain on extinguishment being recorded in other (expense) income related to the difference between the carrying value of the liability and its estimated fair value on the date of amendment.

Income Taxes

Since May 2018, we have not recorded any income tax benefits for NOLs. We believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. Accordingly, we have established a valuation allowance against such deferred tax assets for all periods since inception.

We assess our income tax positions and records tax benefits based upon management's evaluation of the facts, circumstances, and information available at the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, we record the amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions for which it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the financial statements.

We had no provision for income taxes for the year ended December 31, 2023. We recorded a benefit for income taxes of $1.0 million for the year ended December 31, 2022 which consisted of approximately $0.1 million of current federal tax benefit and $0.9 million of current state tax benefit. The 2022 tax benefit is attributed to the reversal of the company's uncertain tax position due to the lapse of the 2018 Pennsylvania statute of limitations concerning the timing of the payment received under the Original Ligand Agreement.

As of December 31, 2023, we had federal and state NOL carryforwards in the amount of $36.7 million and $37.6 million, respectively, which may be available to offset future taxable income. The state NOL carryforwards begin expiring at various dates through 2038, unless previously utilized. All federal NOL carryforwards were generated subsequent to January 1, 2018 and therefore are able to be carried forward indefinitely. As of December 31, 2023, we had orphan drug credits of $0.2 million to reduce future federal taxes through 2039.

Results of Operations

Comparison of Three Months Ended September 30, 2024 and 2023

The following sets forth our results of operations:

	Three Months Ended September 30,		Change	
	2024	2023	$	%
Operating expenses:				
Research and development	$ 3,182	$ 1,096	$ 2,086	190%
General and administrative	1,880	457	1,423	311%
Total operating expenses	5,062	1,553	3,509	226%
Operating loss	(5,062)	(1,553)	(3,509)	(226)%
Other (expense) income:				
Interest expense – royalty agreement	(1,017)	(1,298)	281	22%
Interest expense – convertible notes payable	(220)	-	(220)	(100)%
Fair value adjustments on derivative liabilities	(75)	(52)	(23)	(44)%
Fair value adjustments on convertible notes payable	(568)	-	(568)	(100)%
Other income, net	167	71	96	135%
Net loss	$ (6,775)	$ (2,832)	$ (3,943)	(139)%

Research and Development Expenses

The table below summarizes our research and development expenses incurred by development program:

(in thousands)	Three Months Ended September 30, 2024	2023	Change $	Change %
QTORIN rapamycin for PC and GS	$ -	$ 511	$ (511)	(100)%
QTORIN rapamycin for microcystic LM	637	9	628	6,979%
QTORIN rapamycin for VM	73	-	73	100%
QTORIN rapamycin CMC costs	847	227	620	273%
Non-program specific and unallocated research and development expenses:				
Salaries and stock-based compensation	1,021	174	847	487%
Consultants	354	100	254	255%
Other	250	75	175	233%
Total research and development expenses	$ 3,182	$ 1,096	$ 2, 086	190%

For the three months ended September 30, 2024, research and development expenses were $3.2 million, compared to $1.1 million for the three months ended September 30, 2023. The increase in research and development expenses during the three months ended September 30, 2024 was primarily due to higher salaries and stock-based compensation costs of $0.8 million, CMC costs of $0.6 million, and microcystic LM program spending of $0.7 million. Partially offsetting this increase was a decrease in PC and GS programs as a result of the 2023 second quarter readouts of the PC and GS clinical trials.

General and Administrative Expenses

For the three months ended September 30, 2024, general and administrative expenses were $1.9 million, compared to 0.5 million for the three months ended September 30, 2023. The increase in general and administrative expenses during the three months ended September 30, 2023 was primarily due to an increase in professional services and legal costs as a result of the activity associated with the Merger Agreement.

Other (Expense) Income

Other (expense) income for the three months ended September 30, 2024 and 2023 was ($1.7) million and ($1.3) million, respectively. The increase in other expense of $0.4 million was primarily attributable to interest expense and fair value adjustments on the convertible notes payable that were issued in 2024, partially offset by a decrease in royalty agreement interest expense.

Comparison of Nine Months Ended September 30, 2024 and 2023

The following sets forth our results of operations:

	Nine Months Ended September 30, 2024	2023	Change $	Change %
Operating expenses:				
Research and development	$ 5,608	$ 8,094	$ (2,486)	(31)%
General and administrative	4,121	2,359	1,762	75%
Total operating expenses	9,729	10,453	(724)	(7)%
Operating loss	(9,729)	(10,453)	724	(7)%
Other income (expense):				
Interest income/ (expense) – royalty agreement	(2,764)	7,407	(10,171)	(137)%
Interest expense – convertible notes payable	(249)	-	(249)	(100)%
Fair value adjustments on derivative liabilities income/ (expense)	(404)	541	(945)	(175)%
Fair value adjustments on convertible notes payable	(568)	-	(568)	(100)%
Other income, net	231	657	(426)	(65)%
Net income (loss)	$ (13,483)	$ (1,848)	$ (11,635)	(630)%

Research and Development Expenses

The table below summarizes our research and development expenses incurred by development program:

	Nine Months Ended September 30,		Change	
(in thousands)	**2024**	**2023**	**$**	**%**
QTORIN rapamycin for PC and GS	$ -	$ 3,232	$ (3,232)	(100)%
QTORIN rapamycin for microcystic LM	1,064	175	889	508%
QTORIN rapamycin for VM	73	-	73	100%
QTORIN rapamycin CMC costs	1,000	785	215	27%
Non-program specific and unallocated research and development expenses:				
Salaries and stock-based compensation	2,373	1,871	502	27%
Consultants	705	1,652	(946)	(57)%
Other	393	379	14	4%
Total research and development expenses	$ 5,608	$ 8,094	$ (2,486)	(31)%

Research and development expenses for the nine months ended September 30, 2024 were $5.6 million compared to $8.1 million for the nine months ended September 30, 2023. The decrease in research and development expenses during the nine months ended September 30, 2024 was due to decreased program and consulting expenses incurred from the PC and GS programs as a result of the 2023 second quarter readouts of the PC and GS clinical trials and partially offset by increased microcystic LM program spending as well as increased salary and stock-based compensation expenses.

General and Administrative Expenses

For the nine months ended September 30, 2024, general and administrative expenses were $4.1 million compared to $2.4 million for the nine months ended September 30, 2023. The increase in general and administrative expenses during the nine months ended September 30, 2024 was primarily due to increased professional services and legal costs associated with the Merger Agreement.

Other Income (Expense)

Other income (expense) during the nine months ended September 30, 2024 was ($3.8) million of expense as compared to $8.6 million of income during the nine months ended September 30, 2023. During the second quarter of 2023, we received data from certain of our clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization, resulting in a significant reduction in the expected future royalty payments and a corresponding reduction in the royalty agreement liability. We incurred non-cash interest income (expense) related to the royalty agreement of ($2.8) million and $7.4 million for the nine months ended September 30, 2024 and 2023.

Comparison of Fiscal Years Ended December 31, 2023 and 2022

The following sets forth our results of operations:

	Year Ended December 31,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 8,793	$ 13,884	$ (5,091)	(37)%
General and administrative	3,076	4,156	(1,080)	(26)%
Total operating expenses	11,869	18,040	(6,171)	(34)%
Operating loss	(11,869)	(18,040)	6,171	34%
Other income (expense):				
Interest income/ (expense) - royalty agreement	6,265	(10,364)	16,629	160%
Fair value adjustments on derivative liabilities income/ (expense)	485	(300)	785	262%
Gain on extinguishment - royalty agreement	23,098	-	23,098	100%
Other income, net	712	126	586	465%
Income/ (loss) before income taxes	18,691	(28,578)	47,269	165%
Income tax - (expense) benefit	-	1,026	(1,026)	(100)%
Net income (loss)	$ 18,691	$ (27,552)	$ 46,243	(168)%

Research and Development Expenses

The table below summarizes our research and development expenses incurred by development program:

	Year Ended December 31,		Change	
(in thousands)	2023	2022	$	%
QTORIN rapamycin for PC and GS	$ 3,682	$ 5,684	$ (2,002)	(35)%
QTORIN rapamycin for microcystic LM	164	961	(797)	(83)%
QTORIN rapamycin CMC costs	878	2,561	(1,683)	(66)%
Non-program specific and unallocated research and development expenses:				
Salaries and stock-based compensation	2,383	2,795	(412)	(15)%
Consultants	1,229	1,222	7	1%
Other	457	661	(204)	(31)%
Total research and development expenses	$ 8,793	$ 13,884	$ (5,091)	(37)%

Research and development expenses for the year ended December 31, 2023 were $8.8 million compared to $13.9 million for the year ended December 31, 2022. The decrease in research and development expenses during the year ended December 31, 2023 was due to decreased expenses incurred from the PC and GS programs as a result of the 2023 readouts of the PC and GS clinical trials as well as decreased CMC costs across all programs.

General and Administrative Expenses

For the year ended December 31, 2023, general and administrative expenses were $3.1 million compared to $4.2 million for the year ended December 31, 2022. The decrease in general and administrative expenses during the year ended December 31, 2023 was primarily due to decreases in personnel-related costs as a result of salary reductions in the second half of 2023 following the readouts of the PC and GS clinical trials.

Other Income (Expense)

Other income (expense) during the year ended December 31, 2023 was $30.6 million of income as compared to ($10.5) million of expense during the year ended December 31, 2022. During the second quarter of 2023, we received data from certain of our clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization, resulting in a significant reduction in the expected future royalty payments and a corresponding reduction in the royalty agreement liability. We incurred non-cash interest income (expense) related to the royalty agreement of $6.3 million and ($10.4) million for the years ended December 31, 2023 and 2022. In addition, we recorded a $23.1 million gain on extinguishment of the royalty agreement liability in connection with the Amended Ligand Agreement in November 2023.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, our operations have been financed primarily by aggregate net proceeds of $76.5 million from the issuance of convertible preferred stock and convertible notes, and $15.0 million received under the Ligand Agreements. We will continue to be dependent upon equity and debt financings, collaborations or other sources of third-party capital at least until we are able to generate positive cash flows from product sales, if ever.

We incurred net losses of $6.8 million and $2.8 million for the three months ended September 30, 2024 and 2023, respectively. We incurred net losses of $13.5 million and $1.8 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $89.8 million and cash and cash equivalents of $14.2 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and, to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in accounts payable and accrued expenses.

Going Concern

Our financial statements included elsewhere in this prospectus have been prepared on a basis which assumes we do have sufficient funds to support operations through the one-year period from the issuance of the September 30, 2024 and 2023 financial statements. In December 2024, we closed the merger receiving $11.4 million of cash from the public company and an additional $66.0 million from the closing of the PIPE, of which $60.0 million was from PIPE investors and $6.0 million was received from convertible notes. The total PIPE was $78.4 million in total cash, of which $18.4 million was received under convertible notes and $60.0 million was received at the closing of the PIPE. As discussed in Note 1 to those financial statements, we have incurred losses from operations and negative cash flows from operations, and does not expect to generate revenues or operating cash flows for the foreseeable future.

Future Funding Requirements

We have not generated product revenue or achieved profitability since our inception and expect to continue to incur net losses for the foreseeable future. As of December 13, 2024, we had approximately $80.0 million in cash and cash equivalents, net of deal expenses. Based on our current business plans, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operations for the one year period following the date of this filing. Moreover, we expect our losses to increase as it continues to advance our product candidates through clinical trials and regulatory submissions. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the closing of the Merger, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our primary uses of capital have been, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, license payments or milestone obligations that may arise, manufacturing costs, legal and other regulatory expenses and general overhead costs.

Based upon our operating plan, we believe that the net proceeds from the PIPE Financing, together with our available cash and cash equivalents upon the closing of the Merger, will be sufficient to fund our operating expenses into the second half of 2027. To continue to finance our operations beyond that point, we may need to raise additional capital, the success of which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. If we receive regulatory approval for QTORIN rapamycin for the treatment of microcystic LM, or any of our future product candidates, we expect to incur significant commercialization expenses related to manufacturing, sales, marketing, and distribution, or from any out licensing of the product. We are also responsible for up to $5.0 million in milestone payments to Ligand under the Amended Ligand Agreement upon the achievement of certain regulatory milestones by us related to QTORIN rapamycin, which may be triggered prior to the commercialization of any of our product candidates and ability to generate revenue. Please see "*—Critical Accounting Policies and Significant Judgments and Estimates—Ligand Agreement*" and "*Our Business-Ligand Development Funding Agreement*".

We will continue to require additional capital to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund our operations for the foreseeable future. We may finance our cash needs through public or private equity or debt offerings or other third party sources such as strategic collaborations. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on terms that are acceptable to us, or at all. To the extent that we raise additional capital by issuing equity securities, our existing stockholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences detrimental to the rights of our common stockholders. Any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future funding requirements depend on many factors, including, but not limited to:

- timing and outcome of regulatory review for QTORIN rapamycin for the treatment of microcystic LM, or our other product candidates;
- the cost of commercialization and manufacturing activities with respect to QTORIN rapamycin and our ability to successfully commercialize this product candidate, if approved;
- the scope, progress, results and costs of researching and developing QTORIN rapamycin, or any future product candidates, and conducting preclinical studies and clinical trials;
- the number and scope of clinical programs we decide to pursue;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with developing our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- Our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing and sales of any future approved products, if any;
- the potential size of the markets for our approved products, if any;

- the timing and amount of milestone or royalty payments due under the Ligand Agreements or under similar arrangements with any future collaboration or licensing partners;
- the expenses needed to attract and retain skilled personnel;
- Our need to implement additional internal systems and infrastructure, including financial and reporting systems, and other costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio

Further, our development and commercialization operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities and commercialization of QTORIN rapamycin, if approved. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we may be unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Net cash (used in) provided by:		
Operating activities	$ (5,447)	(11,276)
Financing activities	12,304	-
Net increase (decrease) in cash and cash equivalents	$ 6,857	(11,276)

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2024 and September 30, 2023 consisted of net income for the period adjusted for non-cash items and changes in components of operating assets and liabilities. For the nine months ended September 30, 2024, a net loss of ($13.5) million was adjusted for non-cash items of $8.0 million, including non-cash interest expense of $2.8 million, change in fair value of derivative liabilities-royalty agreement of $0.4 million, change in fair value of convertible notes payable of $0.6 million, stock-based compensation expense of $0.6 million, and a net increase of $3.4 million due to changes in operating assets and liabilities. For the nine months ended September 30, 2023, net loss of ($1.8) million was adjusted for non-cash items of $9.4 million, including non-cash interest income of $7.4 million, change in fair value of derivative liabilities-royalty agreement of ($0.5) million, stock-based compensation expense of $0.5 million, and a net decrease of $1.9 million due to changes in operating assets and liabilities.

Net cash provided by financing activities

For the nine months ended September 30, 2024, net cash provided by financing activities were $12.3 million, entirely attributable to proceeds from issuance of convertible notes payable of $12.4 million less issuance costs of $0.1 million.

The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (13,703)	$ (14,840)
Financing activities	5,000	9,566
Net decrease in cash and cash equivalents	$ (8,703)	$ (5,274)

Net cash used in operating activities

Net cash used in operating activities for the years ended December 31, 2023 and December 31, 2022 consisted of net income for the period adjusted for non-cash items and changes in components of operating assets and liabilities. For the year ended December 31, 2023, a net income of $18.7 million was adjusted for non-cash items of $32.3 million, including gain on extinguishment of royalty agreement of ($23.1) million, non-cash interest income of ($6.3) million, change in fair value of derivative liabilities-royalty agreement of ($0.5) million, stock-based compensation expense of $0.6 million, and a net decrease of $3.1 million due to changes in operating assets and liabilities. For the year ended December 31, 2022, a net loss of $27.6 million was adjusted for non-cash items of $12.6 million, including non-cash interest expense of $10.4 million, change in fair value of derivative liabilities-royalty agreement of $0.3 million, stock-based compensation expense of $0.4 million, and a net increase of $1.6 million due to changes in operating assets and liabilities.

Net cash provided by financing activities

For the years ended December 31, 2023 and December 31, 2022, net cash provided by financing activities consisted of $5.0 million and $9.6 million, respectively, primarily attributable to proceeds from the Amended Ligand Agreement and issuance of Series D preferred stock, respectively.

Contractual Obligations and Commitments

Leases

We lease office space in Wayne, Pennsylvania. Our future lease payments for these facilities is $0.1 million for the remaining term, which automatically renewed in October 2024.

Ligand Agreement

In December 2018, we entered into the Original Ligand Agreement with Ligand, whereby Ligand agreed to make a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. As partial consideration for the one-time payment, we granted Ligand the right to receive up to $8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by us related to QTORIN rapamycin for the treatment of any and all indications. The total amount of potential future milestone payments remaining under the arrangement were $5.0 million as of December 31, 2023. In addition, we agreed to pay to Ligand tiered royalties from 5.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. On a licensed product-by-licensed product and country-by-country basis, the royalty period is from the date of first commercial sale of such licensed product in a country until the latest of (i) the expiration of the last valid claim within the licensed patent rights covering such licensed product in the country in which such licensed product is made, used or sold, (ii) the expiration of the regulatory exclusivity term conferred by the applicable regulatory authority in such country with respect to such licensed product, and (iii) the fifteenth anniversary of the first commercial sale of such licensed product in such country.

In November 2023, we and Ligand entered into the Amended Ligand Agreement, whereby Ligand paid us an additional $5.0 million in return for an increase in the future tiered royalties to 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin.

Other

Further, we enter into contracts in the normal course of business with service providers for clinical trials, preclinical research studies and testing, manufacturing, and other services and products for operating purposes. Our payment obligations under these contracts generally provide for termination upon notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of any such payments or if and when they will occur.

We may also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments or long-term commitments of cash.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on the audited financial statements included elsewhere in this prospectus, which have been prepared in accordance with GAAP in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to the audited financial statements included elsewhere in this prospectus, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses and Accruals

We estimate costs of research and development activities conducted by service providers, which include, the conduct of sponsored research, preclinical studies and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued expenses and other current liabilities or prepaid expenses and other current assets on the balance sheets and within research and development expense on the statements of operations.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust accrued liabilities or prepaid expenses. While our actual results could differ from their estimates, we have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical trial investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify estimates of accrued expenses accordingly on a prospective basis

Ligand Agreement

Under the terms of the Ligand Agreements, we received $15.0 million to fund the development of QTORIN rapamycin, in exchange for Ligand's right to receive future payments based on the development and commercialization of products covered under the Ligand Agreements. Ligand is entitled to receive up to an additional $5.0 million of milestone payments upon the achievement of certain regulatory milestones by us related to QTORIN rapamycin for the treatment of any and all indications. Our obligation to make milestone payments under the Ligand Agreements was determined to be a derivative liability, and our obligation to make future royalty payments was determined to be a debt instrument.

The accounting for liabilities under the Ligand Agreements requires us to make certain estimates and assumptions about the timing and probability of FDA approval and commercialization, and the amount of future net sales for any product containing QTORIN rapamycin. The estimated future net sales are based on subjective assumptions that include the estimated size of the addressable patient population and the anticipated pricing of the Company's products. These assumptions are subject to significant variability, and are thus subject to significant uncertainty.

Royalty payments will be recorded as debt service payments on the royalty agreement liability. Interest expense is determined using the effective interest method based upon risk adjusted cash flow estimates of our expected future royalty payments, yielding an effective interest rate of 38.9% and 30.3% as of December 31, 2023 and 2022, respectively. The effective interest rate is estimated at each balance sheet date based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. This effective interest rate will likely be subject to variability as we continue the development and commercialization of our products. The derivative liabilities — royalty agreement is classified as long term on our balance sheet according to the estimated timing of the occurrence of potential payments.

The fair value of the derivative liabilities — royalty agreement with respect to the potential milestone payments is determined based upon the estimated probabilities and timing of the achievement of milestones, discounted to present value using our estimated weighted average cost of capital. The assumptions used to determine the fair value of the derivative liabilities — royalty agreement at December 31, 2023 and 2022 were (a) weighted cost of capital of 25%; and (b) 50% probability of achieving regulatory approval of a product by the FDA with a term of 3.5 and 1.75 years, respectively. Gains and losses arising from changes in fair value of the derivative liabilities — royalty agreement are recognized within our statements of operations as fair value adjustments on the derivative liabilities — royalty agreement and in the balance sheet as a non-current liability for each financial reporting period.

Our estimates and assumptions with respect to the royalty agreement liability and derivative liabilities — royalty agreement are likely to change as we develop and commercialize QTORIN rapamycin, if approved. Any such adjustments that may become necessary will impact the recorded value of the royalty agreement liability and the derivative liabilities — royalty agreement, the accretion of interest expense on the royalty agreement liability and the fair value adjustments on derivative liabilities — royalty agreement.

Stock-Based Compensation

We account for stock-based compensation in accordance with Accounting Standards Codification, Compensation-Stock Compensation, or ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award.

We use the Black-Scholes option pricing model, or "Black-Scholes", to determine the fair value of our stock options. Black-Scholes utilizes various assumptions, including the fair value per share of the underlying common stock issuable upon exercise of the options, the expected life of the options, the expected stock price volatility from peer companies and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for our common stock and lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. We used the simplified method to calculate the expected term for options granted whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

As a result, if other assumptions had been used, stock-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, stock-based compensation cost could be materially impacted in future periods.

We will continue to use judgement in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes, our policy is to account for forfeitures as they occur in accordance with ASC 718. We reverse compensation expense cost previously recognized, in the period the award is forfeited, for an award that is forfeited before completion of the requisite service period.

Determination of Fair Value of Common Stock on Grant Date

As our common stock has not been publicly traded, we periodically estimated the fair value of the our common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the AICPA", Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our stock valuations were prepared using either a hybrid method, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or a probability-weighted expected return method, or "PWERM", where the fair value of common stock is estimated based upon an analysis of future values for the Company, assuming various outcomes. Under the PWERM, the common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. In addition to considering the results of these third-party valuations, we considered various objective and subjective factors to determine the price of its common stock as of each grant date, which may be as of a date later than the most recent third-party valuation date.

Recently Adopted Accounting Pronouncements

Refer to Note 2, "*Summary of Significant Accounting Policies*," in the notes to our audited financial statements for the periods ended September 30, 2024 and December 31, 2023 appearing elsewhere in this prospectus for a discussion of recent accounting pronouncements.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Item 10 of Regulation S-K and is not required to provide the information otherwise required under this item.

BUSINESS

On December 13, 2024, we completed the previously announced business combination with Legacy Palvella in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Legacy Palvella, with Legacy Palvella surviving as our wholly owned subsidiary (such business combination, the Merger). In connection with the completion of the Merger, we changed our name from "Pieris Pharmaceuticals, Inc." to "Palvella Therapeutics, Inc.," and our business became primarily the business conducted by Legacy Palvella. We are now a clinical-stage biopharmaceutical company focused on developing and, if approved, commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no FDA-approved therapies. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code.

As used in this Business Section, the words "Company," "we," "our," "us" and "Palvella" refer, collectively to Palvella Therapeutics, Inc. and its consolidated subsidiaries following completion of the Merger.

Overview

We are a clinical-stage biopharmaceutical company whose vision is to become the leading rare disease biopharmaceutical company focused on developing and, if approved, commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no FDA-approved therapies. We intend to leverage our versatile QTORIN platform to treat these patients. QTORIN is designed to generate new therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of rare genetic skin diseases. Our lead product candidate, QTORIN rapamycin, is in clinical development for two of these diseases: microcystic LM, and cutaneous venous malformations. QTORIN rapamycin contains the active pharmaceutical ingredient rapamycin, also known as sirolimus, which is an inhibitor of mTOR, a kinase that plays a key role in cell growth and proliferation.

We currently have one ongoing clinical trial and one clinical trial planned to start in the fourth quarter of 2024. Our ongoing trial, SELVA, is a Phase 3 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin in the Treatment of Microcystic LM. We previously announced topline Phase 2 clinical trial results from the multi-center, open-label study of 12 subjects receiving QTORIN™ rapamycin once-daily for 12-weeks. The Phase 2 clinical trial featured multiple pre-specified efficacy assessments, including clinician and patient global impression assessments as well as assessments of individual clinical manifestations that are important disease burdens for individuals living with microcystic LMs. All participants in the Phase 2 clinical trial demonstrated improvements on the Clinician Global Impression of Change scale, with all participants in the study rated as either "Much Improved" (n=7, 58%) or "Very Much Improved" (n=5, 42%) after 12-weeks of treatment compared to the pre-treatment baseline period. We expect to report top-line data for the Phase 3 study in approximately 40 participants with microcystic LM in the first quarter of 2026.

Microcystic LM is a serious, chronically debilitating, and lifelong disease of the lymphatic system characterized by lymphorrhea and acute cellulitis. It is estimated that there are more than 30,000 diagnosed patients in the United States with microcystic LM. The specific pathophysiology of microcystic LM is primarily the result of somatic activating mutations in PIK3CA which result in increased activation of the PI3K/mTOR pathway and subsequent lymphatic hyperplasia. Because microcystic LM has a well-understood pathophysiology and a well-defined disease course, we believe an appropriate clinical study for this rare disease is a baseline-controlled Phase 3 study using clinician assessments.

We have received Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation from the FDA for QTORIN rapamycin for the treatment of microcystic LM. We have also received Fast Track Designation from the FDA for the treatment of venous malformations.

There are no FDA-approved therapies currently indicated for either microcystic LM or cutaneous venous malformations. If approved for the treatment of microcystic LM or cutaneous venous malformations, we believe QTORIN rapamycin has the potential to become the standard of care for these diseases.

We also have a planned study for cutaneous venous malformations, a Phase 2 Baseline-Controlled Study Evaluating the Safety and Efficacy of QTORIN rapamycin for the Treatment of Cutaneous Venous Malformations expected to start in the fourth quarter of 2024. Cutaneous venous malformations are a serious disease with a high unmet need characterized by dysregulated growth of malformed veins impacting the skin, causing functional impairment and deformity. It is estimated that there are more than 75,000 diagnosed patients in the United States with cutaneous venous malformations. We are conducting a Phase 2 baseline-controlled clinical trial in approximately 15 participants in this patient population and expect to report top-line data in the fourth quarter of 2025.

We also have additional preclinical research programs based on our QTORIN platform for the treatment of serious, rare genetic skin diseases for which we believe there are significant unmet needs. As we plan to expand our pipeline into new rare skin diseases, we plan to generate new product candidates with our QTORIN platform. Despite our intentions with respect to our QTORIN platform, our business carries substantial risks. The QTORIN platform is novel and has only generated one program to date, QTORIN rapamycin, and clinical evidence to support this candidate is preliminary and limited at this time.

We have multiple patents and patent applications directed to anhydrous gel formulations of rapamycin, including QTORIN rapamycin, and the use of such anhydrous gel formulations for the treatment certain skin disorders, including microcystic LM and venous malformations. Our issued U.S. patents with claims directed to certain anhydrous gel formulations containing rapamycin and methods of treatment expire in 2038.

We have assembled a management team with extensive experience in building and operating innovative biopharmaceutical companies across a variety of therapeutic areas and technologies. Our management team is led by Wesley H. Kaupinen, our founder, President and Chief Executive Officer, who previously served as Senior Vice President of Corporate Development and Commercialization at Insmed, Inc. and has 20 years of broad leadership and management experience in the life sciences industry. Our executive team is composed of individuals with deep experience in rare disease drug development including Kathleen Goin, our Chief Operating Officer, who previously served in leadership roles at Trevena, Inc and Endo Pharmaceuticals, Inc and Jeffrey Martini Ph.D., our Chief Scientific Officer, who previously served in leadership roles at Marinus Pharmaceuticals, Teva Pharmaceuticals, and Cephalon, Inc. Members of our management team have previously led various discovery, development, manufacturing and commercialization programs within the rare disease and dermatology fields, including ARIKAYCE, Differin, Diflucan, VALCHLOR, ZTALMY, and Vectical. Further, we are supported by a leading group of investors including, among others, Adams Street Partners, BVF Partners L.P., CAM Capital, Petrichor, and Samsara BioCapital.

We have assembled a medical and scientific advisory board, or MSAB, comprised of leading scientists and academic clinicians who have backgrounds in various disciplines, including genetics, rare skin diseases, and novel therapeutic discovery and development. Our partners with our MSAB for idea generation into high unmet need diseases in need of novel therapeutic development, scientific and clinical input on clinical study design including endpoints, and generation of new product candidate ideas.

Our Vision and Approach

Our vision, supported by our mission of serving patients, is to become the leading rare disease biopharmaceutical company focused on developing and, if approved, commercializing novel therapies for serious, rare genetic skin diseases, for which there are no FDA-approved therapies. We envision a future treatment paradigm in which individuals suffering from serious, rare genetic skin diseases, and the physicians treating those diseases, have significantly improved treatment options which address the underlying causes of those diseases. The core components of our approach include the following:

- *supported by our pipeline, build upon our experience in serious, rare genetic skin diseases through indication expansion and the generation of new product candidates.* We believe serious, rare genetic skin diseases represent a substantial opportunity to develop and, if approved, commercialize first-in-disease therapies. More than 98% of the reported 597 rare skin diseases do not have a therapy approved by the FDA. Our goal is to select diseases caused by genetic mutations with a well-understood etiology, pathophysiology and a strong rationale for a specific pathway intervention, many of which have a debilitating, lifelong impact on individual lives. In addition to exploring other selected diseases for which QTORIN rapamycin could provide a viable therapy, we are investigating several new product candidates for additional rare genetic skin diseases that it selects;

- *maximize the potential of the QTORIN platform across a wide range of molecules.* To date, we have developed QTORIN rapamycin which we believe has broad clinical potential in several serious, rare genetic skin diseases without FDA-approved therapies. We intend to further leverage our scalable QTORIN platform to generate additional product candidates that target the known causes of serious, rare genetic skin diseases for which there are no FDA approved therapies; and
- *forge meaningful patient and physician collaborations.* A key element of our approach is to take a rigorous, systematic approach to understanding the disease of the patient populations that we are addressing. A foundational pillar of this approach is to forge and maintain meaningful collaborations with physicians and disease advocacy organizations. Through this engagement, valuable learnings inform the selection and development of efficacy endpoints and what constitutes clinical meaningfulness and acceptable risk-benefit. We believe these learnings significantly inform our product development approach, which may contribute to the regulatory acceptability of our product candidates.

Our Strategy

To achieve our vision, the key elements of our strategy include:

- *successfully develop and, if approved, commercialize QTORIN rapamycin for the treatment of microcystic LM, cutaneous venous malformations and other rare genetic skin diseases.* QTORIN rapamycin is in clinical development for microcystic LM and cutaneous venous malformations. There are no FDA-approved therapies for these specific indications, and, if approved, we believe QTORIN rapamycin has the potential to become the standard of care. We expect to report top-line data from our Phase 3 SELVA trial in microcystic LM in the first quarter of 2026. Assuming favorable results from SELVA, we plan to request FDA agreement to begin a rolling submission of an NDA in the second half of 2026. We plan to initiate our Phase 2 trial in patients with cutaneous venous malformations in the fourth quarter of 2024 and expect to report top-line data in the fourth quarter of 2025. Given there is a growing body of real-world evidence that rapamycin has the potential to treat a broad number of cutaneous diseases, we plan to evaluate QTORIN rapamycin in other cutaneous indications;
- *build an independent commercial organization to commercialize, if approved, our genetic skin diseases therapies in the United States.* If approved for the treatment of microcystic LM and/or cutaneous venous malformations in the United States, we intend to independently commercialize QTORIN rapamycin by building out a focused specialty sales force that will target vascular anomaly centers and dermatologists who cover the majority of patients being treated. We expect this will provide us with a significant competitive advantage in addition to providing it future operational leverage. Outside of the United States, we may consider building our own commercial infrastructure or out license where appropriate, elect to utilize strategic collaborators, distributors or other partners to assist in the commercialization of our products candidates, if approved;
- *evaluate the potential of the QTORIN platform to treat additional rare genetic skin diseases.* As noted above, more than 98% of the reported 597 rare skin diseases do not have a therapy approved by the FDA. We have identified several rare genetic skin diseases where there are no FDA approved therapies, and the cause of pathophysiology or genetic mutation is known. The QTORIN platform provides the opportunity to target delivery of active pharmaceutical ingredients (APIs) with a very diverse chemical structure and size to the dermis and epidermis with limited systemic absorption. The incorporation and evaluation of alternative APIs in the QTORIN platform would expand the possible range of indications for which novel, life-changing therapies may be created. This provides the opportunity for expansion of novel QTORIN products to address the needs of hundreds of thousands of patients with genetic skin diseases who have no FDA approved therapies for their disease; and
- *continue to establish barriers to entry through intellectual property and regulatory exclusivities.* We have significant intellectual property rights in our current development programs, including issued patents in the U.S. directed to QTORIN rapamycin and methods of using such anhydrous gel formulations of Exrapamycin. We own issued patents in the US, as well as Australia, China, Israel and Japan and pending applications in the US, Europe and Japan directed to anhydrous gel formulations of rapamycin and methods of using the same to treat certain skin disorders, including microcystic LM and venous malformations that naturally expire in 2038. We also own issued US patents and a pending US application that encompass anhydrous gel formulations of mTOR inhibitors, including rapamycin, and methods of using the same to treat skin disorders including microcystic LM and venous malformations that naturally expire as early as 2038. We also own pending applications in the US and other major markets directed to the use of QTORIN rapamycin for the treatment of microcystic LM that, if issued, would expire in 2042. Any of our product candidates that receive regulatory approval may also potentially be protected by regulatory exclusivity, such as through the exclusive marketing period provided from Orphan Drug Designation and/or drugs approved based on new clinical investigations (other than bioavailability studies) that are conducted by the sponsor that are essential to approval. We expect to continue to expand our intellectual property portfolio as we continue to develop our product candidates.

Our QTORIN Platform

Our research team developed and designed QTORIN by testing over 80 combinations of excipients. QTORIN is a patented and versatile platform designed to generate potential new therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of rare skin diseases. Identification and development of novel QTORIN products begins with our team identifying serious, rare genetic skin diseases with no FDA-approved therapies which clinically have a localized presentation and therefore could be suitable for targeted, topical drug intervention. Once target diseases are selected and key biological pathways that can be causative drivers of that specific disease have been identified, a rigorous formulation development process is undertaken with product development objectives of achieving (i) high payloads of the active pharmaceutical ingredient in the anhydrous gel, and (ii) penetration and distribution of pharmacologically active quantities of the active ingredient to the site of pathophysiology, including the dermis, while achieving minimal to no systemic absorption of the active ingredient.

The QTORIN platform is composed of an anhydrous gel comprising excipients, or inactive substances, that serve as the vehicle or medium for a drug or other active substance, selected in what we believe is an optimized ratio in order to achieve therapeutic levels of drug delivered to the site of origin of the disease, often within the deepest regions of the skin. Our QTORIN product candidates have been developed to accommodate the cargo at high concentrations in order to drive sufficient drug to our target deep in the epidermis and dermis. Inclusion of agents like penetration enhancers have been avoided in order to minimize systemic absorption. The final formulation of the drug product is designed to be less than 100% of the maximum solubility to avoid physical instability due to factors such as temperature change.

We believe our QTORIN platform provides the following advantages:

- *reproducible platform across multiple molecules.* In a preclinical study conducted by us, the QTORIN platform has demonstrated compatibility with more than 15 high potential pharmacologic agents. As a result of such compatibility, we believe it will be able to generate new product candidates and reproduce the formulations results from QTORIN rapamycin while minimizing the challenges and timelines typically associated with formulation development activities;
- *versatility across a range of indications.* We believe QTORIN's ability to accommodate a wide range of therapeutic cargoes enables versatility in the targets for molecular intervention, thereby potentially being able to develop novel QTORIN therapies across a diverse set of serious, rare genetic skin diseases;
- *tailored penetration and distribution of molecules to the site of where the disease originates.* In order to engage the target, a product candidate must deliver therapeutic concentrations of drug substances to the site of the pathophysiology, which is often rendered challenging due to certain agents, such as rapamycin, possessing high molecular weights or structures that prevent skin penetration. By optimizing the individual QTORIN excipient ratio for each therapeutic molecule, our platform is designed to deliver therapeutic agents to the specific site of disease origin;
- *delivery of therapeutic agents designed to minimize systemic exposure.* Well-accepted mechanisms of action of rapamycin or other therapeutic agents represent potential therapies for rare genetic skin diseases. However, the adverse event profile of those agents through systemic exposure poses significant barriers to patient adoption. As observed in all completed clinical trials with QTORIN rapamycin to date, our QTORIN product candidates are designed for targeted, localized delivery of therapeutic agents to pathogenic tissue of interest while minimizing systemic absorption and thereby reduce the risk of unwanted adverse events associated with systemic therapy;

- *enhanced stability at ambient temperatures.* We have data to support long-term stability of QTORIN rapamycin at room temperature, which we believe is an important feature for patient acceptability, particularly for a chronic dosing regimen; and
- *scalable QTORIN manufacturing.* We intend to scale up QTORIN manufacturing in the future. Under cGMP conditions, we believe it has overcome many of the challenges associated with manufacturing QTORIN rapamycin, including solubility, stability, and scalability. Based on our work to date, we believe that we can successfully scale up QTORIN rapamycin and future QTORIN product candidates to meet our future development and commercial needs.

Despite our intentions with respect to our QTORIN platform, therapeutic development with a novel platform carries substantial risks. The QTORIN platform is novel and has only generated one program to date, QTORIN rapamycin, and clinical evidence to support this candidate is preliminary and limited at this time. In addition, as a novel platform, the QTORIN platform may never result in a product candidate that receives regulatory approval. Our Phase 2b clinical trial of QTORIN rapamycin in patients with Gorlin Syndrome and Phase 3 clinical trials of QTORIN rapamycin in patients with pachyonychia congenita failed to meet their respective primary endpoints. Past and any future failures in any one QTORIN-based program may decrease trust in our technology and may affect our ability to conduct clinical programs for other QTORIN-based product candidates.

The Role of mTOR in Cutaneous Disorders

The PI3K/mTOR family of kinases play vital roles in cellular function by regulating proliferation, growth and survival. Dysregulation of the PI3K/mTOR pathway is associated with several cutaneous disorders, including serious, rare genetic skin diseases. Often these pathological diseases are characterized by hyperproliferation and tumorigenesis, defective keratinocyte differentiation, senescence-like growth arrest and resistance to apoptosis.

Key to Medical Abbreviations: ANG: angiopoietin, VEGF: vascular endothelial growth factor, VEGFR: vascular endothelial growth factor receptor, PIK3CA: phosphoinositide 3-kinase, mTOR

Over the past two decades, several studies have been published on the use of oral rapamycin in cutaneous diseases, including genetic skin diseases, due to rapamycin's well-documented anti-proliferative, anti-angiogenic, and immunosuppressive properties.

Rapamycin Challenges and Our Novel Product Candidate, QTORIN Rapamycin

Rapamycin Has Demonstrated Activity in Rare Genetic Skin Diseases

A systematic review by Swarbrick and colleagues found over 200 publications demonstrating the broad potential of rapamycin in cutaneous diseases. This publication built upon an early publication by Teng and colleagues in May 2015 which highlighted the substantial promise of mTOR inhibitors, including rapamycin, in a number of difficult to treat dermatologic diseases while advocating for targeted, topical approaches suited to improve tolerability. Despite the preliminary evidence of clinical benefit in many cutaneous diseases, rapamycin's use in cutaneous diseases, including rare genetic skin diseases, remains limited, primarily due to the undesirable toxicity profile of oral rapamycin, including immunosuppression, for cutaneous diseases and the limited biodistribution of oral rapamycin to the dermis.

Barriers to Oral Rapamycin's Use in Cutaneous Diseases

Rapamycin is FDA approved as an oral product for the prevention of organ transplant rejection and for the treatment of lymphangioleiomyomatosis. It has been well-established that inhibition of mTOR by rapamycin has the potential to have broad application in dermatology, but there are several challenges which have limited our use:

- systemic exposure to oral rapamycin is associated with severe and unwanted toxicities. In addition to our immunosuppressive nature, the most common (≥30%) adverse reactions observed in clinical studies for organ rejection prophylaxis include: peripheral edema, hypertriglyceridemia, hypertension, hypercholesterolemia, increased creatinine and constipation, along with several other intolerable adverse reactions. Additionally, because rapamycin suppresses immune function, chronic systemic use may cause serious side effects such as thrombocytopenia and hyperlipidemia, nephrotoxicity and altered insulin sensitivity;

- oral rapamycin has low biodistribution to the skin which limits the clinical activity of the systemic mode of administration against genetic skin diseases;

- rapamycin is a challenging molecule to formulate and deliver topically as its high molecular weight, poor solubility and chemical instability restrict penetration into the deeper layers of the skin, including the dermis, where many manifestations of rare genetic skin diseases originate. Rapamycin has a molecular weight of 914 daltons, almost two-fold higher than the generally accepted rule that the molecular weight of a compound should be under 500 daltons to penetrate the skin;

- the listed drug for the Section 505(b)(2) NDA intends to reference is oral RAPAMUNE (Reference sponsor: Pfizer). We intend to rely on the FDA's conclusions of safety from its review of the reference sponsor's studies, along with our generated data, to support approval. These include nonclinical mammalian systemic toxicity, gene toxicology, carcinogenicity, and safety pharmacology studies. Clinical studies include systemic safety, PK, and PD studies.

Our Novel Product Candidate: QTORIN rapamycin

We have developed QTORIN rapamycin, a novel, 3.9% anhydrous topical gel formulation containing rapamycin, for the treatment of microcystic LM and cutaneous venous malformations. If approved, we believe QTORIN rapamycin has the potential to become the standard of care in each of these diseases.

We believe it has optimized QTORIN rapamycin to deliver therapeutically active levels of rapamycin to the deep layers of the skin, including the dermis, with minimal systemic absorption below immunosuppressive levels. We estimate, based on preclinical studies, that QTORIN rapamycin will deliver concentrations of rapamycin — approximately 1000-fold higher than oral rapamycin — to the cutaneous tissue with minimal systemic absorption. During the discovery and development of QTORIN rapamycin, 25 excipients were evaluated in more than 80 different combinations. QTORIN rapamycin was designed to utilize a combination of excipients that we believe maximized solubility while maintaining chemical stability. QTORIN rapamycin has completed formulation optimization and *in vitro* penetration assays and has demonstrated low systemic absorption in Our human clinical trials to date.

QTORIN Rapamycin for the Treatment of Microcystic LM

Objective	● We are developing QTORIN rapamycin for the treatment of microcystic LM ● There are no FDA-approved therapies; We are developing the first targeted therapy for microcystic LM
Our Targeted Approach	● Utilizing QTORIN to confer site-directed delivery of rapamycin to the dermis where microcystic LM originates
Program Status; **Upcoming Milestones**	● We completed our Phase 2 clinical trial in the 4th quarter of 2022 ● We initiated our Phase 3 clinical trial in the 3rd quarter of 2024. ● We expect to report top-line data in first quarter of 2026
Disease Burden	● Serious, rare and chronic genetic disease characterized by lymphorrhea and acute cellulitis ● Usually present at birth; progresses throughout life ● Localized masses of malformed lymphatic vessels protrude through the skin barrier

Genetic Basis and Molecular Pathways	● Somatic gain of function mutation primarily in PIK3CA leads to hyperactivated PI3K/mTOR signaling
Scientific Rationale	● mTOR is hyperactivated in microcystic LM ● Rapamycin directly inhibits overactivated mTOR activity and decreases lymphangiogenesis
Market Dynamics	● Estimated prevalence: > 30,000 diagnosed patients in US ● Based on >30,000 diagnosed patients in the U.S., we believe the estimated TAM opportunity on an annualized basis is greater than $1 billion
Intellectual Property; Regulatory Designations*	● We hold U.S. patents and applications in the U.S. and major foreign markets with claims directed to anhydrous gel formulations of rapamycin and methods of use for treating microcystic LM, expiring in 2038 and, for certain applications, if issued, as late as 2042 ● FDA Fast Track Designation ● FDA Orphan Drug Designation ● FDA Breakthrough Therapy Designation ● European Medicines Agency Orphan Drug Designation

* *Fast Track or Orphan Drug Designation may not result in a faster development process, review or approval as compared to conventional FDA approval procedures. Please see "Special FDA Expedited Review and Approval Programs" herein for more information.*

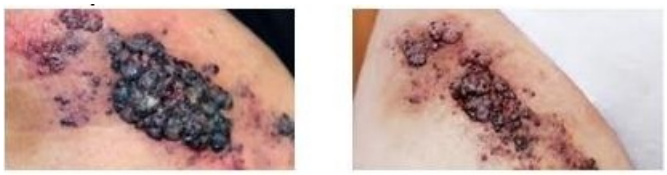
Disease Overview

Microcystic LM is a serious, rare genetic disease of the lymphatic system characterized by lymphorrhea, which is the persistent discharge of internal lymph fluid from disrupted lymphatic vessels, and acute cellulitis, or a bacterial infection of the skin underlying tissues (Figure 1). Microcystic LM primarily arise from somatic activating mutations in PIK3CA resulting in hyperactivation of the PI3K/mTOR signaling pathway. Microcystic LM is one of three morphologic types of LMs based on the size of the individual cysts (as opposed to the overall size of the LM): macrocystic (>2cm), microcystic (<2cm) and combined. Microcystic LM present at birth and is the result of congenital abnormalities of the lymphatic system thought to originate during the embryologic development of lymphatic vessels. Microcystic LM leads to malformed lymphatic vasculature, persistent infiltration of lymph fluid into soft tissues, and locally invasive masses with pathologic sequelae.

Due to the chronic lymphorrhea, cellulitis and other symptoms, microcystic LM is associated with a high degree of morbidity and has a significant impact on daily life. Microcystic LM can be located on any region of the body but is most commonly found in high areas of lymphatic vessels, including the trunk, head and neck. The malformations connect to the epidermis in the form of vesicles, papules, and plaques which can leak at the surface. Infections of malformations can occur and may lead to cellulitis of surrounding tissues or severe, life-threatening infections. The natural history of microcystic LM is progressive, with symptoms generally worsening during life, including increases in the number size of cysts that lead to complications, and morbidity.

Microcystic LMs arise due to post zygotic mutations during early embryonic development, are usually present at birth, and are persistent and progressive throughout life. Patients are usually diagnosed at a young age by pediatric dermatologists or pediatric hematologists and are managed by multi-disciplinary teams. Due to the genetic nature of the disease, microcystic LM is programmed to be on the skin and do not spontaneously regress. In a 2017 review of 153 patients over a 34-year period to determine if LM sub-types had spontaneous regression, spontaneous regression was observed in 0% of patients with microcystic LM (n=28;TABLE 1).

FIGURE 1. Example of Microcystic LM



Despite the high rate of morbidity and life-threatening cellulitis associated with microcystic LM, there are currently no FDA-approved medications for this disease. Currently available treatment options include surgery, sclerotherapy with bleomycin or other sclerotic agents, laser, and cryotherapy, which are invasive, can induce further inflammation and result in high recurrence rates. Surgical resection remains challenging and ineffective due to the infiltrative, diffuse nature of microcystic LM. In addition, due to underlying associated somatic mutation, it is difficult to achieve accurate and clear surgical margins, resulting in high recurrence rates post resection. The high unmet need and drawbacks associated with surgical approaches have spurred the search for treatment alternatives that target the underlying pathological mechanisms of this disorder.

Microcystic LM Does Not Have Spontaneous Regression

Due to the genetic nature of the disease, microcystic LMs are persistent and progressive throughout life, without spontaneous regression. A review article, which followed subjects over a 34-year observation period, found no spontaneous regression throughout that time among 28 participants with microcystic LM (Table 1).

TABLE 1: Clinical Characteristics of Spontaneous Regression of the LM Patients

Types	Microcystic
Subtotal	28
Sex (F:M)	14:14
Age (y), mean ± SD	0.89 ± 1.4
Maximum diameter (cm), mean ± SD	—
Spontaneous regression	
Positive	0
Negative	28

Because microcystic LM does not have spontaneous regression, a baseline-controlled study, in which subjects' status on therapy is compared with the status before therapy, can be suitable for this disease because improvement does not reflect the natural history of the disease in the absence of treatment and can therefore be attributed to be a direct therapeutic effect.

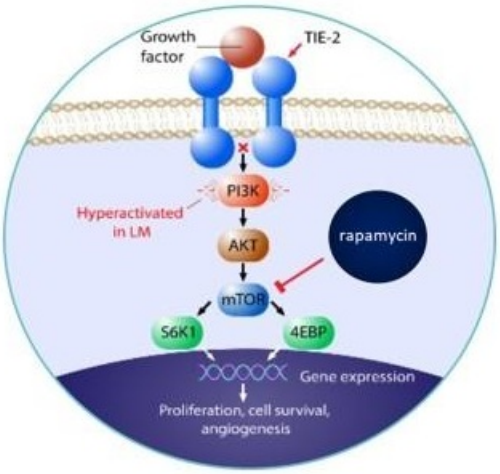
Discovery of mTOR as key driver of microcystic LMP

Important insights gained over the last decade have implicated increased activation of the PI3K/mTOR signaling pathway in microcystic LM. Enhanced mTOR signaling has been observed to increase the expression of the vascular endothelial growth factor, or VEGF, a key promoter of angiogenesis and lymphangiogenesis. This leads, in turn, to uncontrolled, disorganized, and malformed lymphatic development.

Hyperactivation of the PI3K/mTOR pathway results in lymphatic endothelial cell proliferation and migration, defective mural cell coverage and aberrant lymphatic vascular network formation. This ultimately results in the anatomic malformations in lymphatic channels seen in this disease.

Rapamycin inhibits mTOR, which is a downstream element of the over-activated PI3K/mTOR pathway (Figure 2). Rapamycin demonstrated in preclinical studies an ability to decrease mTOR signaling, thereby reducing endothelial cell proliferation and subsequently the formation of malformed lymphatic vessels. Additionally, rapamycin reduces lymph fluid formation in the affected tissue, helping to minimize clinical symptoms associated with microcystic LM.

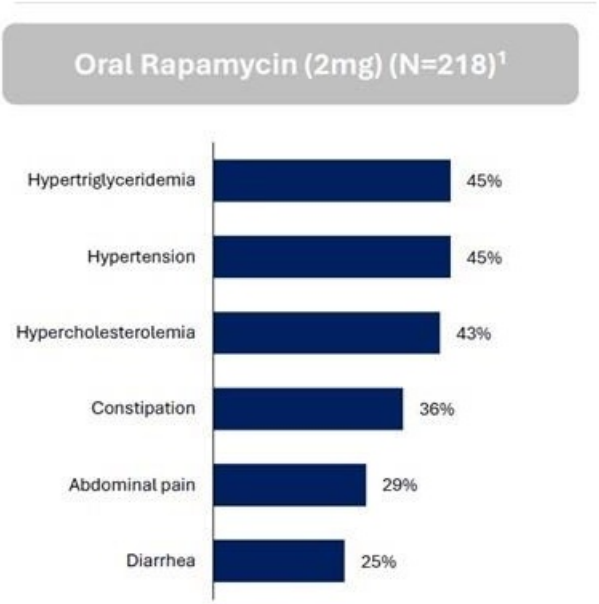
FIGURE 2. PI3K/mTOR Pathway Is Overactivated in Microcystic LM and Point of Rapamycin Pharmacologic Inhibition



A large and growing evidence base exists demonstrating rapamycin's activity in treating microcystic LM: since 2011, a total of 16 studies evaluating the off-label use of rapamycin in microcystic LM have been published. In a 2021 article by Kalwani *et al*, the authors stated "Sirolimus [rapamycin], a strong inhibitor of mTOR, has shown tremendous promise in the treatment of LM." Systematic reviews of rapamycin for the treatment of microcystic LMs have demonstrated that rapamycin can significantly improve the prognosis.

Oral rapamycin is sometimes used in clinical practice in leading academic vascular anomalies clinics where microcystic LM patients are often treated. Importantly, off-label use of oral rapamycin is associated with an adverse event profile that requires frequent patient monitoring and limits its use for a chronic disease such as microcystic LM (Figure 3). Particularly for pediatric and adolescent patients, these toxicities limit the use of oral rapamycin. In addition, oral rapamycin is associated with a narrow therapeutic window due to the adverse event profile described above and the poor biodistribution of oral rapamycin to the dermis, which is where microcystic LMs originate.

FIGURE 3. Adverse Events Observed with Oral Rapamycin Treatment In the Study of Prophylaxis of Organ Rejection Following Renal Transplantation



As a result, there remains a significant unmet need for a targeted rapamycin therapy for microcystic LM that limits systemic absorption and the adverse effects, or AEs, associated with systemic therapy.

Advancing QTORIN Rapamycin in Microcystic LM

We are evaluating QTORIN rapamycin for the treatment of microcystic LM. QTORIN rapamycin has the potential to be the first therapy and standard of care in the U.S. for microcystic lymphatic malformations, if approved.

Based on preclinical studies, we believe that QTORIN rapamycin will deliver concentrations of rapamycin approximately 1000-fold higher than systemic rapamycin to the cutaneous tissue with minimal systemic absorption. We therefore believe that QTORIN rapamycin has the potential to harness the potential therapeutic benefits of rapamycin while minimizing the well-known side effects of oral rapamycin.

We completed an open-label Phase 2 trial to evaluate QTORIN rapamycin in patients with microcystic LM in the 4th quarter of 2022. Results of that trial are detailed below. Based on those results and discussions with the FDA at a Type C Meeting in 2023 and a Type B Breakthrough Therapy Meeting in 2024 regarding the proposed patient population, dosing, and endpoint selection for our next clinical trial, We have initiated a Phase 3 trial, SELVA (PALV-09), to evaluate QTORIN rapamycin in patients with microcystic LM in the 3rd quarter of 2024. We expect to report top-line data from this trial in the first quarter of 2026.

QTORIN rapamycin has been granted FDA Fast Track Designation, Orphan Drug Designation, and Breakthrough Therapy Designation for the treatment of microcystic LM.

Clinical Development Overview

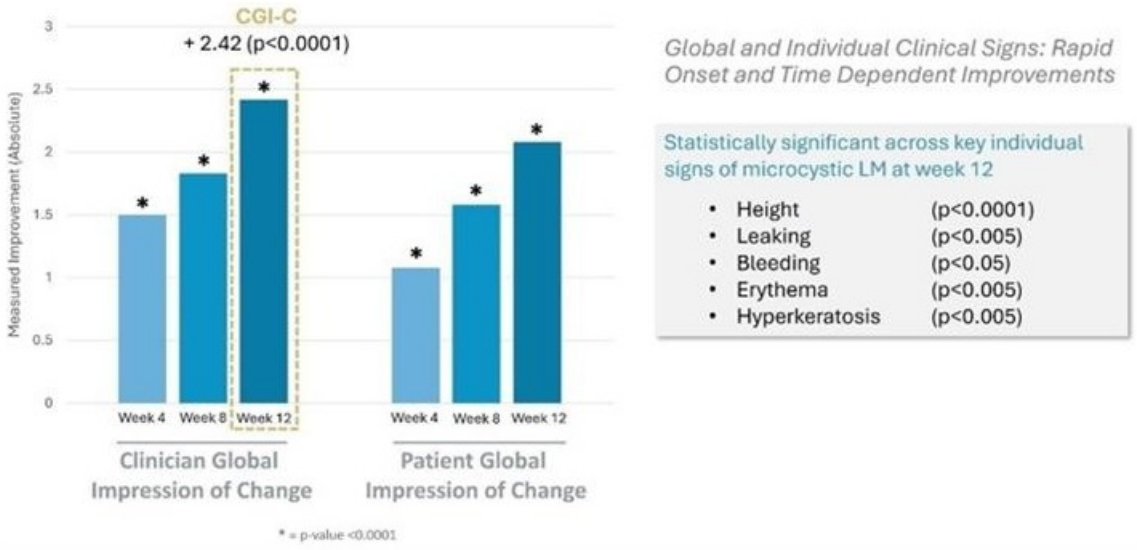
We completed an open-label, Phase 2 trial (PALV-06) with QTORIN rapamycin in patients with microcystic LM and based on the results of that trial, Breakthrough Therapy Designation was granted to QTORIN rapamycin for the treatment of microcystic LM. A subsequent Breakthrough Therapy Designation meeting with the FDA was held and the study was initiated in the third quarter of 2024.

PALV-06 Overview and Efficacy Results

The Phase 2 PALV-06 trial was a multi-center, open-label study of subjects receiving QTORIN™ rapamycin once-daily for 12-weeks. The Phase 2 clinical trial featured multiple pre-specified efficacy assessments, including clinician and patient global impression assessments as well as assessments of individual clinical manifestations that are important disease burdens for individuals living with microcystic LMs. As is common in Phase 2 studies, efficacy was evaluated as secondary endpoints without multiplicity adjustment or formal statistical analysis. The PALV-06 trial enrolled a total of 12 participants, all of whom completed 12-weeks of QD QTORIN rapamycin treatment as well as all study related activities.

A baseline-controlled study is a clinical study in which the patient's condition during treatment is compared with their condition before treatment. In such studies, participants serve as their own control. In a placebo-controlled study, patients are randomized prior to treatment to receive either study drug or matching placebo and to determine how the efficacy of the treatment compares to placebo. Baseline-controlled studies are appropriate when the effects are dramatic, occur rapidly following treatment, and are unlikely to have occurred spontaneously (e.g., general anesthesia, cardioversion, measurable tumor shrinkage).

FIGURE 4: PALV-06 Improvement in Clinician- and Patient- Reported Impression of Change



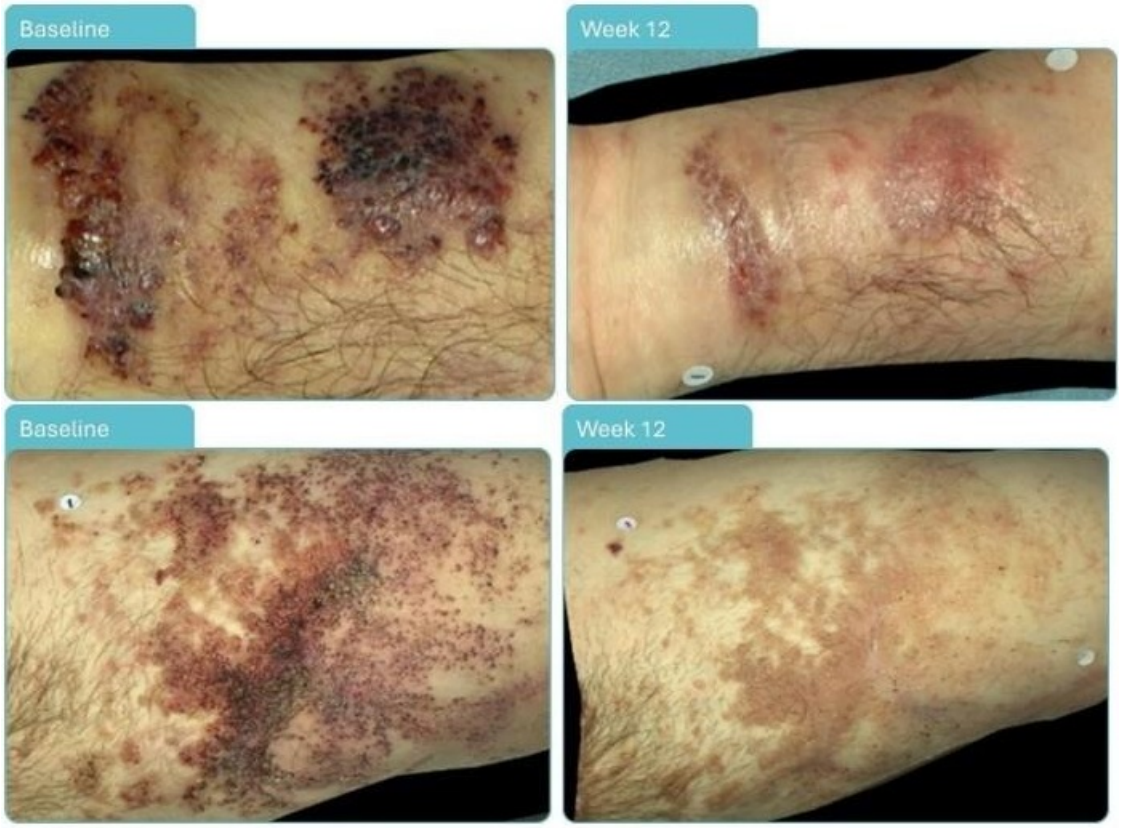
Efficacy data from the Phase 2 open-label study demonstrated nominally statistically significant and clinically meaningful improvements for microcystic LM participants treated with QTORIN rapamycin on several of the efficacy endpoints studied. The data demonstrated improvements as compared to pre-treatment (baseline) across several clinically relevant and important endpoints, including many of the static and impression of change global instruments (Table 2). Statistically significant improvements in the clinician global impression of severity (CGI-S), clinician global impression of change (CGI-C), and patient global impression of change (PGI-C) were supported by visual improvements of target lesions captured in photographs. Clinical meaningfulness was confirmed by participant interviews.

TABLE 2: PALV-06 Study Efficacy Results on Clinician- and Patient-Reported Impression of Change Instruments As Compared to Pre-Treatment (Baseline)

Efficacy Endpoints	**Week 12** Mean (n=12)	**Nominal, Two-sided p-value**
Clinician Global Impression of Change (CGI-C)	2.42	*<0.0001*
Clinician Global Impression of Severity (CGI-S) – Overall	-1.33	*<0.0001*
• CGI-S Height	-1.67	*<0.0001*
• CGI-S Leaking	-0.92	*0.0047*
• CGI-S Bleeding	-0.92	*0.0197*
• CGI-S Erythema	-1.08	*0.0016*
• CGI-S Crusting/Hyperkeratosis	-1.17	*0.0012*
Patient Global Impression of Change (PGI-C)	2.08	*<0.0001*
CGI-C and PGI-C improvements are represented by increases; CGI-S improvements are represented by reductions CGI-C and PGI-C are 7-points scales ranging from "Very Much Worse" (-3) to "Very Much Improved" (+3) CGI-S is a 5-point lesion severity scale p-values are nominal as there was no adjustment for multiplicity amongst efficacy endpoints All p-values from paired t-tests vs mean change of 0 as compared to baseline		

In addition to meaningful improvements in clinician- and patient-reported outcomes, visible improvement in lesions was observed following treatment with QTORIN rapamycin.

FIGURE 5: Visible Improvement in Microcystic LM Lesions During QTORIN Rapamycin Treatment in PALV-06



PALV-06 Phase 2 Pharmacokinetic and Safety/Tolerability Results

Systemic concentrations of rapamycin following administration of QTORIN rapamycin in the PALV-06 trial were <2 ng/mL for all participants at all time points tested with an average of 120-98 pg/mL across all patients and time points tested. Safety data obtained in the PALV-06 trial was similar to that observed in larger clinical studies of QTORIN rapamycin, including clinical trials in Pachyonychia Congenita (PALV-02, -03, -05) and Gorlin Syndrome (PALV-04). QTORIN rapamycin was generally well tolerated with all treatment related adverse events either mild or moderate. No study participants discontinued or withdrew from the study. No SAEs, clinically significant lab abnormalities or vital sign abnormalities were reported. The most common TRAEs occurring in >2 participants were application site pain (n=3, 25.0%), application site pruritus (n=3, 25.0%), and nausea (n=2, 16.7%).

TABLE 3: PALV-06 Treatment Related Adverse Events in Microcystic LM Participants

TREATMENT RELATED AES	RELATED ANY GRADE EVENTS (N=12, %)
Application site pain	3 (25)
Application site pruritus	3 (25)
Nausea	2 (16.7)
Application site discharge	1 (8.3)
Application site erythema	1 (8.3)
Application site paraesthesia	1 (8.3)
Nodule	1 (8.3)
Eczema	1 (8.3)
Skin exfoliation	1 (8.3)
Diarrhea	1 (8.3)
Headache	1 (8.3)

Phase 3 trial – PALV-09 (SELVA) and Anticipated pre-NDA Meeting

We designed our Phase 3 trial (Figure 6) based on results from the Phase 2 trial and consideration of comments from the FDA during End of Phase 2 and Breakthrough Therapy Designation Meetings. Discussions with the FDA focused on several aspects of the proposed clinical trial design, including the patient population, dosing, and endpoint selection. The FDA commented on each of these areas and advised where further clarification was requested.

Subsequent to the Breakthrough Therapy Designation Meeting and incorporation of certain FDA feedback into the Phase 3 trial design, We were notified in September 2024 that we had received an FDA Orphan Drug Clinical Trials Grant for up to $2.6 million to support our Phase 3 trial of QTORIN rapamycin for the treatment of microcystic LM. Since the program's inception, the FDA has awarded approximately 700 Orphan Products Clinical Trial Grants to fund clinical trials of products evaluating the efficacy and/or safety in support of a new indication or change in labeling to address unmet needs for patients with rare diseases or conditions. Grant applications are peer reviewed and evaluated for scientific and technical merit by a panel of experts in the subject field of the specific application. Consultation with the relevant FDA review division may also occur during this phase of the review to determine whether the proposed study will provide acceptable data that could contribute to product approval. A score is assigned to each application based on the scientific/technical review criteria including:

- rationale
- study design
- inclusion of patient input
- investigator(s)
- infrastructure
- financial resources
- ability to advance the current field.

The review panel may advise the Orphan Products Grant program staff about the appropriateness of the proposal to the goals of the grant program. Since inception, the FDA Orphan Products Grants Program has funded clinical trials that have facilitated the approval of more than 85 products. Our receipt of the grant does not guarantee FDA approval of QTORIN rapamycin for the treatment of microcystic LM or any other indication.

The Phase 3 trial to evaluate QTORIN rapamycin in patients with microcystic LM includes up to 40 participants who will administer QTORIN rapamycin QD for 24+ weeks. The primary and key secondary endpoints are a 7-point change mLM-IGA, a dynamic assessment that uses a comparative rating scale, and a blinded evaluation using the microcystic LM multi-component static scale, respectively. Clinician-reported change in severity from the start of treatment as measured by the mLM-IGA scale is supported by Phase 2 trial results as exit interviews conducted with the clinicians who were part of the trial. More specifically, these data support that clinicians can accurately rate change in microcystic LM disease severity across each level of disease activity. The endpoints have been designed to capture clinical changes in key aspects of a patient’s disease, as reported by the clinicians and patients.

We believe the following supports the use of the mLM-IGA, a dynamic assessment that uses a comparative rating scale, as the primary endpoint:

- the mLM-IGA is an endpoint that was specifically designed for this rare disease population with extensive endpoint development incorporating both physician and patient views; and
- the use of a global instrument was the strong and consistent preference of clinician investigators due to it being a multi-sign/symptom disease.

The FDA has recommended that primary efficacy in the treatment of microcystic LM be evaluated on a static multicomponent assessment scale but recommended that we provide a rationale for selecting the comparative rating scale should we proceed with a comparative rating scale. While static scales were explored, these scores were shown to be less sensitive. Furthermore, the mLM-IGA is different from the traditional comparative rating scales in that investigators must score individual clinical signs before filling out the mLM-IGA and the mLM-IGA leverages baseline photographs to provide more objective scoring.

The mLM-IGA also leverages the well-accepted 7-point dynamic change scale that has been used in FDA labeling across many diseases/therapeutic areas.

We believe that a baseline-controlled study is an appropriate trial in patients with microcystic LM because there is evidence the effects of QTORIN rapamycin in this setting are dramatic and occur rapidly following treatment, and effects are unlikely to have occurred spontaneously. The Phase 2 study was a baseline-controlled study, and provided evidence that the treatment effect with QTORIN rapamycin was dramatic and occurred rapidly as evidenced by nominally significant results at the first timepoint measured, 4 weeks. These effects, as well as any results we may see from the ongoing Phase 3 study, are unlikely to have occurred spontaneously. Microcystic LM has a well-understood pathophysiology and a well-defined disease course such that the natural history of the disease shows that patients with microcystic LM do not have spontaneous regression. Therefore, any improvement can more confidently be attributed to study drug rather than natural fluctuations or spontaneous improvement of the disease. This aligns with the FDA's Draft Guidance on Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), which states “Single-arm trials may be an important option in rare diseases with well-understood pathophysiology and a well-defined disease course.” However, the FDA may not agree microcystic LM is an appropriate setting for a baseline-controlled Phase 3 study and has commented that a placebo-controlled trial or additional trials assessing different clinical endpoints may be required to assess the efficacy of QTORIN rapamycin for the treatment of microcystic LM.

FIGURE 6. Microcystic LM Baseline-Controlled Phase 3 Trial Design

Assuming positive results from the Phase 3 study, we plan to submit a Section 505(b)(2) NDA for QTORIN rapamycin for the treatment of microcystic LM. Our NDA strategy is to provide the clinical evidence generated from the Phase 3 study to demonstrate the safety and efficacy of a treatment in the microcystic LM patient population and combine it with confirmatory evidence from the Phase 2 data, real-world evidence and natural history of the disease. In addition to the Phase 3 safety and efficacy data, we plan to use the Phase 3 trial to bridge QTORIN rapamycin to the oral listed drug based on a cross-study comparison between the PK of QTORIN rapamycin from the Phase 3 trial and the published PK of RAPAMUNE and will rely on the listed drug, RAPAMUNE, for additional components of the NDA. If the Phase 3 trial yields a statistically significant result, we plan to review the nonclinical and clinical data with the FDA at a pre-NDA meeting, including to determine whether additional clinical safety or efficacy trials or additional bridging studies may be required to pursue a Section 505(b)(2) NDA pathway for QTORIN rapamycin.

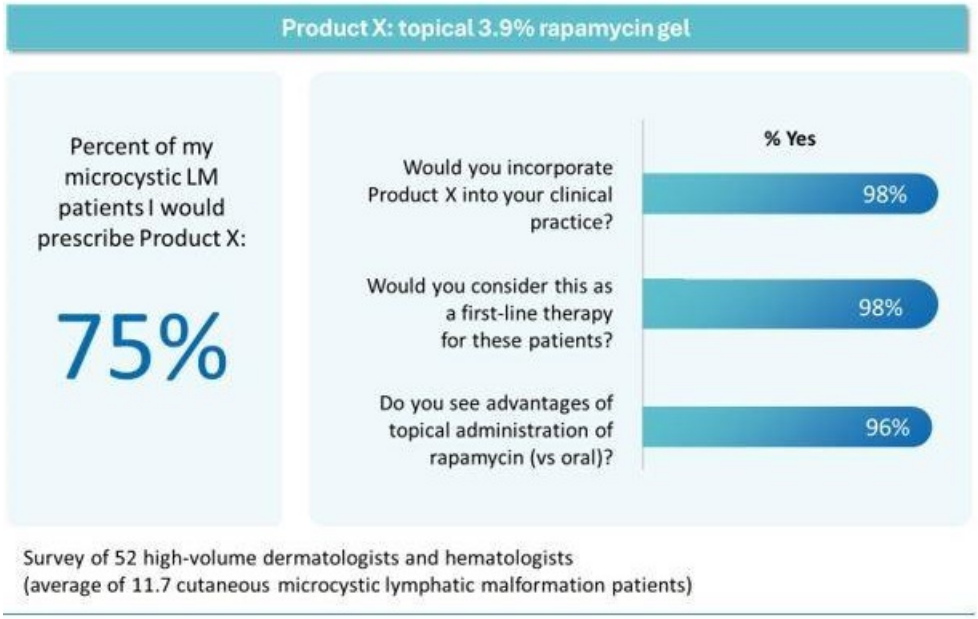
To support our 505(b)(2) NDA, we plan to bridge QTORIN rapamycin and RAPAMUNE based on a cross-study comparison between pharmacokinetic data from QTORIN rapamycin and the prescribing information for RAPAMUNE, the FDA recommends that bridging to support an NDA for the treatment of microcystic LM be done in a relative bioavailability study comparing the pharmacokinetics of a topical product applied under maximal use conditions and the approved oral drug. The planned cross study analysis will allow for comparison of systemic pharmacokinetic parameters, key criteria for assessing the applicability of safety findings from the listed drug, which are a result of systemic exposure from the oral formulation. We believe the proposed clinical pharmacology plan will address the requirements for bridging to support reliance on the FDA's previous findings of safety for RAPAMUNE tablets to support a 505(b)(2) NDA submission by establishing relative bioavailability to known pharmacokinetic parameters of RAPAMUNE as well as pharmacokinetics under maximal use conditions. Population pharmacokinetic analyses, including covariate analyses, will be conducted as data allows. No additional studies are planned, as a bridging approach is planned to enable labeling guidance for specific populations and drug-drug interactions.

Potential Market Opportunity and Market Research

We believe that QTORIN rapamycin, if approved, has commercial potential for microcystic LM in the U.S. The treatment regimen in microcystic LM, we believe, would be chronic dosing due to the genetic nature of the condition. As discussed below, based on a published real-world occurrence study of U.S. physicians, we estimate that there are over 30,000 diagnosed microcystic LM patients in the United States. Furthermore, the introduction of a new treatment may lead to improved awareness of the disease, better and sooner diagnosis, and more patients actively seeking therapy.

As part of better understanding the market opportunity in microcystic LM, we commissioned a primary market research study in May 2024 that surveyed 52 dermatologists and hematologists (Figure 7). Furthermore, as part of our market research, a target product profile, or Product X, was presented based on the Phase 2 results.

FIGURE 7. Market Research Report (May 2024) On Product X



We believe that this preliminary market research underscores both the unmet need and the significant market opportunity for QTORIN rapamycin for the treatment of microcystic LM.

QTORIN Rapamycin for the Treatment of Cutaneous Venous Malformations

Objective	• There are currently no FDA-approved therapies indicated for the treatment of cutaneous venous malformations; We are developing the first targeted therapy
Program Status and Upcoming Milestones	• We plan to initiate our Phase 2 clinical trial in cutaneous venous malformation patients in the 4th quarter of 2024 • We expect to report top-line data in the fourth quarter of 2025
Genetic Basis and Molecular Pathways	• Somatic mutations in TEK or PIK3CA lead to aberrant PI3K/mTOR signaling
Disease Burden	• Cutaneous venous malformations are a serious, rare condition characterized by the overgrowth of veins that protrude through the skin and is characterized by deformities, functional impairment and hemorrhaging • Usually present early in life; progresses throughout life • Localized masses of malformed veins protrude through the skin barrier
Scientific Rationale for Cutaneous Venous Malformations	• TIE2 and PI3K overactivation converge on mTOR • Rapamycin directly inhibits overactivated mTOR activity and decreases endothelial proliferation and venous formation

Our Targeted Approach	• QTORIN is designed to confer site-directed delivery of rapamycin to the epidermis and dermis • Estimated prevalence: >75,000 in the United States • We believe the estimated TAM opportunity on an annualized basis is greater than $1 billion
Intellectual Property; **Regulatory Designations**	• We hold U.S. patents and applications in the U.S. and major foreign markets with claims directed to anhydrous gel formulations of rapamycin and methods of use for treating cutaneous venous malformations, expiring in 2038

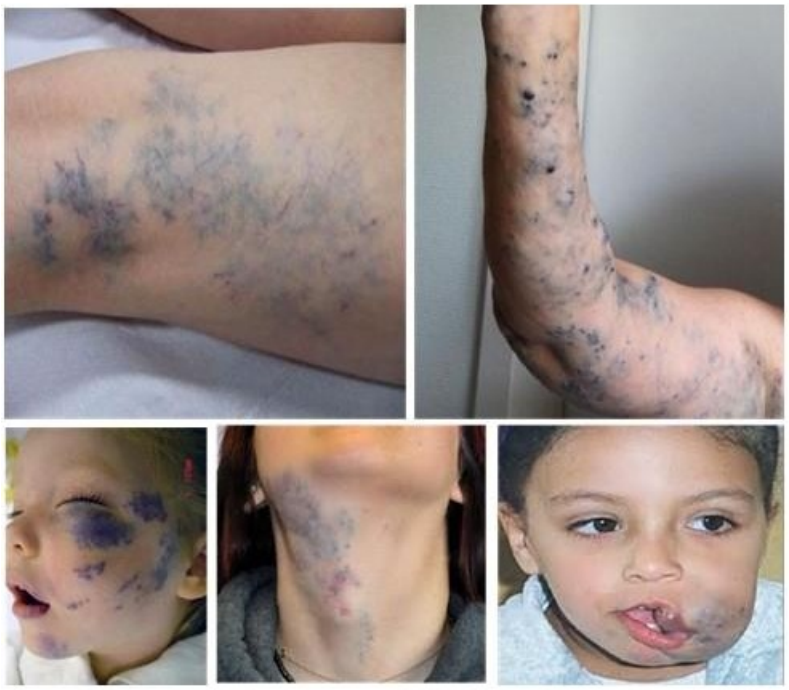
Disease Overview

Cutaneous venous malformations are congenital vascular anomalies characterized by dysregulated growth of veins within the skin. They present as dilated, tortuous vessels that manifest as bluish or purplish patches or nodules on the skin. These malformations result from developmental errors in venous morphogenesis during embryogenesis, leading to abnormal connections between veins and capillaries. These anomalies are typically present at birth and can expand or become more prominent with age. They vary in size and distribution, ranging from small, localized lesions to more extensive areas of affected skin. Cutaneous venous malformations cause functional impairment, significantly impact quality of life and are associated with severe long-term complications.

Management of cutaneous venous malformations depends on factors such as symptomatology, location, and patient preferences. Treatment options, which are limited and insufficient, include conservative approaches such as observation and compression therapy, as well as interventional techniques like sclerotherapy (injection of sclerosing agents to induce vessel shrinkage), laser therapy, and surgical excision for larger or symptomatic malformations. Procedures to remove venous malformations are often not curative, with high rate of recurrence/regrowth. Complications from serial attempts to remove venous malformations including scarring, swelling, and nerve deficits are also compounded when multiple procedures are required. There are no FDA approved treatments for cutaneous venous malformations and there is an urgent need for an approved pharmacologic treatment for these patients.

Cutaneous venous malformations is a chronic disease that worsens over time with no spontaneous regression. The invasiveness and limited effectiveness of current treatments, coupled with the lack of approved pharmacotherapy options, demonstrate the urgent need for an FDA approved therapy for cutaneous venous malformations. A targeted topical therapy that directly addresses disease pathology is of interest to this patient population, as it could abolish the need for systemic treatments that have wider toxicity or invasive procedural interventions.

FIGURE 8. Patients with Cutaneous Venous Malformations



Discovery of mTOR as key driver of Venous Malformations

Cutaneous venous malformations are primarily caused by somatic mutations in either TEK or PIK3CA leading to overactivated PI3K/mTOR signaling. TEK encodes for the endothelial cell-specific receptor tyrosine kinase (TIE2) which in turn activates phosphatidylinositol-3-kinase (PI3K) with mutations in this gene accounting for approximately 70% of cutaneous venous malformation cases. Mutations in the PIK3CA gene, which encodes the p110α catalytic subunit of PI3K, have also been identified in cutaneous venous malformations accounting for approximately 30% of cases that do not have TEK mutations. The PI3K/mTOR pathway plays a crucial role in regulating cell growth, proliferation, and survival. Mutations in TEK or PIK3CA lead to increased activation of this pathway, promoting abnormal endothelial cell proliferation and result in the formation of cutaneous venous malformations. Rapamycin, an mTOR inhibitor, dampens PI3K/mTOR signaling, thus garnering attention as a potential therapeutic option for cutaneous venous malformations.

Our Solution: QTORIN Rapamycin

We are developing QTORIN rapamycin for the treatment of cutaneous venous malformations. Rapamycin inhibits mTOR, which is a downstream element of the PI3K/mTOR pathway. In doing so, rapamycin is thought to diminish PI3K/mTOR overactivation, thereby reducing endothelial cell proliferation and subsequently the formation of malformed vessels. Several published case studies and clinical trials have demonstrated efficacy of the off-label use of oral rapamycin for the treatment of venous malformations.

Clinical Development Overview

We plan to initiate our Phase 2 clinical trial, a 12-week, multicenter, baseline-controlled Phase 2 clinical trial of QTORIN rapamycin in up to 20 patients with cutaneous venous malformations in the 4th quarter of 2024. We plan to enroll patients aged 6 years or older, who will receive treatment for 12 weeks. Assuming favorable results, we plan to meet with the FDA for an end of Phase 2 meeting to discuss a Phase 3 clinical study.

FIGURE 9. PALV-10 Trial Design

Potential Market Opportunity

We believe that QTORIN rapamycin, if approved, has significant commercial potential in cutaneous venous malformations in the U.S. and other markets. The treatment regimen in cutaneous venous malformations, we believe, would be chronic dosing due to the genetic nature of the condition. We estimate, based on published epidemiologic work, that there are >75,000 patients living with cutaneous venous malformations in the United States. Based on this estimated U.S. prevalence, we believe the TAM opportunity on an annualized basis for QTORIN rapamycin in cutaneous venous malformations is greater than $1B. Furthermore, the introduction of a new therapy may lead to improved awareness of these diseases, better and sooner diagnosis, and more patients actively seeking therapy.

Additional mTOR Driven Diseases

We have identified several other rare genetic skin diseases that are driven by mTOR and available clinical data suggests that inhibition of mTOR may be a good therapeutic target in these populations. These diseases include but are not limited to refractory vascular tumors, capillary malformations, and cutaneous sarcoidosis. We are currently evaluating several of these opportunities for clinical development.

Commercialization Strategy

We intend to build commercial infrastructure in the United States to support the commercialization of our product candidates, if approved. We plan to implement a staggered approach to building our commercial team aligned with the progress of our clinical development and advancement towards registration. This approach allows us to grow the organization while appropriately supporting the necessary market development and launch objectives.

The initial focus of our commercial sales effort will be on the subset of multidisciplinary care teams and medical dermatologists at vascular anomaly centers, many of whom we have established relationships through our clinical development initiatives. We plan to engage these physicians by building an experienced rare disease and dermatology-oriented sales force which will be supported by patient consumer and health care provider marketing programs tailored to the indications and communities our products treat. The potential to bring forth new differentiated treatments in rare genetic skin diseases for which no treatments currently exist will help position us to engage this population of physicians. Over time, we hope to generate operational leverage from our field organization as we expand to potential future rare genetic skin diseases indications.

We expect that the patients who are prescribed our product will be serviced by a highly customized support system of programs and resources to support both their access to and appropriate use of our therapies. This will include distribution through specialty pharmacy partners, reimbursement and product administration support through a patient services team trained specifically on the needs of people with rare genetic skin diseases and access programs aimed at providing copay assistance. In certain instances, we may include access to free product through a patient assistance program for eligible individuals. These programs and resources will be built specifically with feedback from the individuals with these diseases and their caregivers in mind. The patient services team will act with the highest levels of integrity and also be highly focused on ensuring that all individuals and physicians who interact with our programs, distribution partners and company have a high level of satisfaction.

To support access to and reimbursement for our therapies, we expect to deploy an experienced patient access team to collaboratively engage with payors, provide education regarding the diseases it treats and provide education regarding our products' value propositions. Value propositions based on clinical data will be key to supporting our product pricing strategies. We plan on engaging with payors leading up to the potential product launch and continuing to support ongoing access creation throughout the life cycle of the product candidate, if approved. As we seek to develop and receive regulatory approval for the treatment of new indications for existing product candidates or develop and commercialize new products, once approved, our patient access team will seek to position itself to provide market access and education.

We expect our commercial organization to be complemented by a medical affairs team tasked with appropriately educating clinical decision makers on the scientific data on the company's products in development, and those that are approved, if applicable. Medical affairs will do this through support of appropriate medical education initiatives, supporting the publication of relevant data at scientific meetings, executing a publication strategy to disseminate new scientific details on our products, and responding to all incoming requests for medical information. We also plan to identify where appropriate the opportunity to support investigator-initiated trials that may expand the scientific body of evidence for our products, and potentially to provide grants to researchers in areas of company interest.

We anticipate that we will be required to invest significant amounts of financial and management resources to develop the appropriate infrastructure to prepare for commercialization. We intend to scale certain investments so that they align with achievement of regulatory hurdles, but significant expenditures may be required prior to the receipt of any regulatory approval of our product candidate.

Outside of the United States, we may consider building our own commercial infrastructure, or out licensing, where appropriate, and may elect in the future to utilize strategic collaborators, distributors, or other partners with making our products available to patients.

Manufacturing

While we have personnel with substantial manufacturing experience, it does not own or operate manufacturing facilities for the production of clinical quantities of our product candidates and we currently have no plans to build our own clinical or commercial-scale manufacturing capabilities. We rely on contract manufacturing organizations, or CMOs, to manufacture and supply our materials to be used for the development and commercialization of our current and any future product candidate and expect such reliance to continue for the foreseeable future. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our current and any future investigational product candidate, as well as our commercial products if marketing approval is obtained. We believe that this strategy allows it to maintain a more efficient infrastructure by eliminating the need for it to invest in our own manufacturing facilities, equipment and personnel while also enabling it to focus our expertise and resources on the development of our current and any future product candidate.

We have agreements with Altasciences and PMRS, both cGMP facilities, for the manufacture of our clinical supply of our product candidate for clinical trials and for the manufacture of a commercial supply of our QTORIN rapamycin, if approved. We have agreements with Medpharm UK for the manufacture of our clinical supply of our product candidate for clinical trials. We obtain supplies of drug substance for our product candidate on a purchase order basis from three sources.

As we advance QTORIN rapamycin through development, it will add backup suppliers for drug product manufacture and packaging to protect against any potential supply disruptions.

Additionally, we have a supply agreement with Nemera, for the supply of pumps it intends to use to package QTORIN rapamycin, if our product candidate is approved. Nemera is a sole source supplier with respect to these pumps, and we are required under the supply agreement to purchase from Nemera. We believe that the Nemera metered dose pump used to deliver our QTORIN rapamycin products will not require separate FDA approval (or approval as a combination product), based upon a preliminary determination from the FDA that the pump is exempt from such requirements. However, if the FDA ultimately disagrees, our product candidate, if approved, may be regulated as a combination products requiring clearance or review of the delivery device by the FDA.

The use of CMOs and reliance on collaboration partners is cost-efficient and has eliminated the need for our direct investment in manufacturing facilities and additional staff early in development. We believe available CMOs are capable of providing sufficient quantities of our product candidate, if approved, to meet anticipated full-scale commercial demands. However, there are a limited number of manufacturers capable of producing our product candidates, particularly our current product candidates which incorporate rapamycin.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product that receives regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of any Palvella product which receives marketing authorization to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. New metrics frequently are used as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. In order to obtain coverage and reimbursement for any product that might be approved for sale, it may be necessary to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the products, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell our products at a profit.

The marketability of any of our current or any future product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. European Union member states may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for product candidates and any of our future product candidates, core technologies, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. our policy is to seek to protect our proprietary position by, among other methods, filing patents and patent applications in the United States and select foreign countries related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also seek to avoid infringing proprietary rights of others. For this reason, we routinely monitor and evaluate third-party patents and publications, and, if necessary, takes appropriate action based on that evaluation. In addition, we rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

As of December 20, 2024, we owned or had an exclusive license to issued U.S. and foreign patents and pending U.S. and foreign patent applications and U.S. provisional applications relating to QTORIN rapamycin and uses thereof. Of these QTORIN rapamycin patents and patent applications:

We own issued patents in the US, as well as Australia, China, Israel and Japan and pending applications in the US, Europe and Japan directed to anhydrous gel formulations of rapamycin and methods of using the same to treat certain skin disorders, including microcystic LM and venous malformations that naturally expire in 2038. We also own issued US patents and a pending US application that encompass anhydrous gel formulations of mTOR inhibitors, including rapamycin, and methods of using the same to treat skin disorders including microcystic LM and venous malformations that naturally expire as early as 2038. We own pending applications in the US, Europe and Japan that are directed to the use of QTORIN rapamycin for the treatment of microcystic LM, which if issued, would naturally expire in September 2042. A summary of these patent families is presented in the following table.

	Owned/Licensed	# Patents and Countries	# Applications and Countries	Natural Expiry Date	Type of Patent
Anhydrous gel formulations of rapamycin and methods of use	Owned by Palvella	9 patents in U.S., Australia, China, Israel, and Japan	4 pending applications in the U.S., Canada, Europe and Japan	January 2038	Utility
Anhydrous gel formulations of mTOR inhibitors and methods of use	Owned by Palvella	2 U.S. Patents	1 pending U.S. application	As early as January 2038	Utility
Use of QTORIN rapamycin for treating microcystic LM	Owned by Palvella	N/A	3; U.S., Europe and Japan	September 2042	Utility

Patent term is based on the filing or grant date of the patent, as well as the governing law of the country in which the patent is obtained. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country.

Obtaining patent protection is not the only method that we employ to protect our propriety rights. We also utilize other forms of intellectual property protection, including trademark, and trade secrets, when those other forms are better suited to protect a particular aspect of our intellectual property. Our belief is that our propriety rights are strengthened by our comprehensive approach to intellectual property protection.

Maintaining the confidential nature of our non-publicly disclosed products and technologies is of paramount importance. For this reason, our employees, contractors, consultants, and advisors are required to enter into nondisclosure and invention assignment agreements when their employment or engagement commences. Those individuals also enter into agreements that prohibit the communication or implementation of any third-party proprietary rights during the course of their employment with us. We also require any third-party that may receive our confidential information or materials to enter into CDAs prior to receipt of that information or material. See "*Risk Factors — Risks Related to Intellectual Property*" for more information.

Ligand Development Funding Agreement

In December 2018, we entered into the Ligand Agreement, or the "Original Ligand Agreement", with Ligand, whereby Ligand agreed to make a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. As partial consideration for the one-time payment, we granted Ligand the right to receive up to $8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by us related to QTORIN rapamycin for the treatment of any and all indications. In addition, we agreed to pay to Ligand tiered royalties from 5.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. On a licensed product-by-licensed product and country-by-country basis, the royalty period is from the date of first commercial sale of such licensed product in a country until the latest of (i) the expiration of the last valid claim within the licensed patent rights covering such licensed product in the country in which such licensed product is made, used or sold, (ii) the expiration of the regulatory exclusivity term conferred by the applicable regulatory authority in such country with respect to such licensed product, and (iii) the fifteenth anniversary of the first commercial sale of such licensed product in such country. In certain circumstances, we have the right to reduce the royalty rates under the Original Ligand Agreement by making payments, or "Royalty Buy Down Payments". Specifically, once we have made royalty payments to Ligand equal to certain specified amounts in the mid eight figures, we have the option to make Royalty Buy Down Payments at any time during the remainder of the term of the Original Ligand Agreement to reduce our certain royalty tier percentages on annual worldwide net sales of any products by one or two percentage points. Such Royalty Buy Down Payments range in size from the low seven figures to the low eight figures.

Ligand may terminate the agreement for any or no reason upon a 90-day notice to us. Ligand may also terminate the agreement for cause in connection with a material breach that we do not cure within a certain period of time.

The total amount of potential future milestone payments remaining under the arrangement were $5.0 million as of December 31, 2023 and 2022. The potential future milestone payments represent derivative liabilities with a fair value of $1.0 million and $1.5 million as of December 31, 2023 and 2022, respectively, which are classified as derivative liabilities – royalty agreement on the balance sheets.

Our obligation under the Original Ligand Agreement was determined to be a debt instrument based on the likelihood of repaying the amounts provided to fund the development of QTORIN rapamycin and that we have significant continuing involvement in the generation of the cash flows potentially due to Ligand. This obligation is reflected as royalty agreement liability which is classified as a long-term liability on the accompanying balance sheets. Interest expense with respect to the royalty agreement liability is determined using the effective interest method based upon risk-adjusted cash flow estimates of our potential future royalty payments under the Ligand Agreement, yielding an effective interest rate of 38.9% and 30.3% as of December 31, 2023 and 2022, respectively. The effective interest rate is estimated at each balance sheet date based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. Changes in these estimates will impact the amount of interest expense recognized through the accompanying statements of operations. During the second quarter of 2023, we received data from certain of our clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization, resulting in a significant reduction in the expected future royalty payments and a corresponding reduction in the royalty agreement liability as of December 31, 2023. We incurred non-cash interest income (expense) of $6.3 million and ($10.4) million for the years ended December 31, 2023 and 2022, respectively, all of which is a component of the royalty agreement liability on the accompanying balance sheets.

In November 2023, the Original Ligand Agreement was amended, or the "Amended Ligand Agreement" and together with the Original Ligand Agreement, the "Ligand Agreements", whereby Ligand paid us an additional $5.0 million in return for an increase in the future tiered royalties to 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin The Royalty Buy Down Payments, and the associated rate modifications, in the Original Ligand Agreement were eliminated as part of the Amended Ligand Agreement. The Amended Ligand Agreement also replaced the termination provision so that the agreement may be terminated by the earlier of a mutual written agreement of the parties or when the royalties contemplated by the agreement are paid to Ligand. We evaluated the accounting for the Amended Ligand Agreement under ASC 470, Debt, and concluded that the present value of the cash flows under the Amended Ligand Agreement differed by more than 10% from the present value of the cash flows under the Original Ligand Agreement. As such, the Original Ligand Agreement was extinguished, and the Amended Ligand Agreement was recorded at the estimated fair value of the royalty agreement liability on the date of the amendment. This resulted in a one-time, non-cash gain on extinguishment of approximately $23.1 million being recorded in the accompanying statement of operations.

The Ligand Agreements require us to make certain estimates and assumptions about the timing and probability of FDA approval and commercialization, and the amount of future net sales for any product containing QTORIN rapamycin. The estimated future net sales are based on subjective assumptions that include the estimated size of the addressable patient population and the anticipated pricing of our products. These estimates and assumptions are subject to significant variability and are thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as we develop and commercialize products containing QTORIN rapamycin that may result in future adjustments to the royalty agreement liability, the derivative liabilities, and the accretion of interest expense.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. Potential competitors with product candidates in development for rare genetic skin diseases include Kaken Pharmaceutical Co., Ltd., Nobelpharma Co., Ltd., Novartis Pharmaceuticals, Relay Therapeutics, Inc. and Vaderis Therapeutics AG. While we believe that our technology, expertise, scientific knowledge and intellectual property provide it with competitive advantages, it faces and will continue to face competition from these companies and other sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. Any product candidates that we successfully develop and, if approved, commercialize may compete with existing therapies or procedures and new therapies that may become available in the future. Moreover, our industry is characterized by the existence of large numbers of patents and frequent allegations of patent infringement.

There are no approved pharmacotherapies currently available for the treatment of microcystic LMs or cutaneous venous malformations. The current treatment options for microcystic LMs include a high-risk surgical procedure and off-label use of sclerosants, including doxycycline, bleomycin, ethanol and sodium tetradecyl sulfate. The current treatment options for cutaneous venous malformations include conservative approaches such as observation and compression therapy, as well as interventional techniques like sclerotherapy, laser therapy and surgical excision for larger or symptomatic malformations. There are a number of drug development companies and academic researchers exploring oral and topical formulations of various agents for the treatment of LMs and VMs including macrolides, phosphodiesterase inhibitors, P13K inhibitors, AKT inhibitors, and mTOR inhibitors. A majority of these are in early development.

The key competitive factors affecting the success of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the level of competition and the availability of coverage and adequate reimbursement from third-party payors. If any of our product candidates are approved and successfully commercialized, it is likely that it will face increased competition as a result of other companies pursuing development of products to address similar diseases.

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 it does. 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 necessary for, our programs. 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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

we may pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive it to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow it to make an appropriate return on our investment.

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 any product candidates that we may develop, and, if approved, successfully commercialize. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our own, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Because of our primary focus on rare diseases, if our product candidates achieve marketing approval, we expect to seek premium pricing.

In addition, some of the market demand for topical rapamycin may be satisfied by compounding pharmacies. Although such pharmacies will be unable to compound any drug that is essentially a copy of QTORIN rapamycin, if approved, a compounded product would not be considered a copy of QTORIN rapamycin if there were a difference between our product and the compounded product that was made for an individual patient and which the prescribing practitioner determines produces a significant difference for that patient. Physicians may determine that such differences exist for some or all of their patients and may choose to prescribe compounded rapamycin provided rapamycin appears on a list established by the FDA of bulk drug substances for which there is a clinical need or satisfies other limited conditions. In the event compounders are authorized to compound rapamycin products following approval of QTORIN rapamycin, if approved, we could be subject to significant competition from those formulations.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA under the Food, Drug, and Cosmetic Act, or FDCA, and other federal and state statutes and regulations. The failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as a clinical hold, the FDA's refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an Investigational New Drug Application, or "IND", which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product CMC, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans.

If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optional dose and regimen, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy and safety of the drug. A single Phase 3 or Phase 2 trial may be sufficient in rare instances, including when either (i) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (ii) the trial is supported by other confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

The manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to disclose, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Furthermore, under the Prescription Drug User Fee Act, or PDUFA, the submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription product. These fees are typically increased annually. An NDA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the NDA includes an indication for other than a rare disease or condition.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. Under PDUFA, the FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. NDAs for most standard review drug products are reviewed within 12 months from submission of NDAs for new molecular entities, or NMEs, and ten months from submission of NDAs for non-NMEs. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. NDAs for most priority review drug products are reviewed within eight months from submission of NDAs for NMEs and six months from submission of NDAs for non-NMEs. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee — typically a panel that includes clinicians, statisticians and other experts — for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the claimed indication.

After the FDA evaluates the NDA and completes clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the application. The applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and the FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Special FDA Expedited Review and Approval Programs

Fast Track Designation

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the disease. The FDA has various programs, including Fast Track Designation, priority review, accelerated approval, and Breakthrough Therapy Designation, the purpose of which is to provide important new drugs or biologics to patients earlier than under standard FDA review procedures.

Under the Fast Track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request. Fast Track designation may not result in a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

If a development product is granted Fast Track Designation, the sponsor may engage in more frequent interactions with the FDA, and the FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs or biologics license application, or BLAs, for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

In addition, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the disease and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug or biologic may be subject to accelerated withdrawal procedures.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition. This generally means a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with the FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that orphan indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product can be considered clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and an exemption from the NDA application user fee.

Breakthrough Therapy Designation

The Breakthrough Therapy Designation is a program by the FDA that aims to speed up the development and review of drugs and biologics for serious or life-threatening conditions. The designation is based on preliminary clinical evidence that the drug may provide a substantial improvement over current therapies.

To qualify for Breakthrough Therapy Designation, the drug must meet the following criteria:

- demonstrate a clear advantage over available therapies;
- have an effect on irreversible morbidity or mortality, or "IMM";
- have an effect on symptoms that represent serious consequences of the disease; and
- have a significantly improved safety profile compared to available therapies.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information in the ClinicalTrials.gov database. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity — patent or nonpatent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements, including, among other things, record-keeping requirements, providing the FDA with updated safety information, product sampling and distribution requirements, and promotion and advertising requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed or promoted only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or take other administrative or judicial enforcement actions if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

NDA applicants are required to list with the FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be referenced by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients, strengths, and routes of administration in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a drug that contains an active moiety that has been previously approved by the FDA in any other NDA, when the application contains reports of a new clinical investigations (other than bioavailability studies) that were essential to approval, that drug product receives three years of exclusivity. During this three-year period of exclusivity, the FDA may not approve any Section 505(b)(2) NDA or ANDA seeking approval of a version of that drug that includes the same conditions of approval.

Section 505(b)(2) NDAs

A special type of NDA, commonly referred to as a Section 505(b)(2) NDA, enables the applicant in certain circumstances to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. A Section 505(b)(2) NDA may provide an alternate path to FDA approval for a new or improved formulation, a new route of administration, or a new use of a previously approved product.

Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. If we choose to rely on the Section 505(b)(2) NDA process to seek approval for our product candidates in various indications, there can be no assurance that the FDA will agree with our use of that pathway. See "*Risk Factors—Risks Related to the Development and Regulatory Approval of Our Product Candidates— Our development and commercialization strategy for our product candidates depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of rapamycin. If we are not able to pursue this strategy, we may be delayed in receiving regulatory authority approval*."

To the extent that the Section 505(b)(2) applicant is relying on the FDA's prior findings of safety or effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Combination Products

A combination product is a product comprised of two or more regulated components, e.g., drug and medical device, that are physically combined and produced as a single entity, packaged together in a single package, or packaged separately but intended to be labeled for use together.

The FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that the FDA determine the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center.

Medical Device Products

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component part, or accessory which is: (i) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices are subject to the FDA's general controls, and any other special controls as deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the devices. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed.

Most medical devices can be legally sold within the United States only if the FDA has: (i) approved a premarket approval application, or PMA, prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices. However, most Class I and some Class II devices can be marketed without prior FDA authorization. If a device falls into a generic category of Class I or Class II devices that the FDA has exempted by regulation, a premarket notification is not required before marketing the device in the United States. Some 510(k)-exempt devices are also exempt from Quality System Regulation, or QSR, requirements.

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA).

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws

In the United States, there are federal and state anti-kickback laws that prohibit offering, the payment, solicitation, or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws apply to manufacturers of products, such as us, with respect to our financial relationship with hospitals, physicians and other potential purchasers or acquirers of our products. The U.S. government has published regulations that identify "safe harbors" or exemptions for certain practices from enforcement actions under the federal anti-kickback statute, and we will seek to comply with the safe harbors where possible. To qualify for a safe harbor, the activity must fit squarely within the safe harbor. Arrangements that do not meet a safe harbor are not necessarily illegal but must be evaluated on a case-by-case basis. A person or entity may be found to violate the anti-kickback statute even absent actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal FCA.

The civil FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not covered by a device's clearance or approval, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. In addition, private payors have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the FCA. Intent to deceive is not required to establish liability under the civil FCA. Civil FCA actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, FCA lawsuits against biopharmaceutical and device companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label uses. Civil FCA liability may further be imposed for known Medicare or Medicaid overpayments that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal FCA. The criminal FCA prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil FCA, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another statute under which medical device companies may potentially be subject to enforcement. Among other things, the civil monetary penalties statue imposes fines against any person who offers to provide remuneration to any individual eligible for benefits under Medicare or Medicaid that the offeror knows or should know is likely to influence the individual to order or receive from a particular provider or supplier of any item or service reimbursable under those programs.

The federal HIPAA also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the Affordable Care Act amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The Sunshine Act requires annual reporting, by applicable device and drug manufacturers, of covered products, payments, and other transfers of value to certain health care providers, and ownership and investment interests held by physicians and their immediate family members.

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

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain states also require implementation of commercial compliance programs and compliance with the medical device industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require companies to track and report information related to payments, and other items of value to physicians and other healthcare providers.

If our operations are found to be in violation of any of the laws or regulations described above or any other applicable laws, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Enforcement actions can be brought by federal or state governments, or as "qui tam" actions brought by individual whistleblowers in the name of the government under the civil FCA if the violations are alleged to have caused the government to pay a false or fraudulent claim.

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

Foreign Corrupt Practices Act

The FCPA, generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals and medical devices are employed by their government, and the purchasers are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. The SEC and DOJ have increased their FCPA enforcement activities with respect to pharmaceutical and medical device companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Enforcement actions may be brought by the DOJ and SEC, and legislation has expanded the SEC's power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent-based claims such as those under the FCPA from five years to ten years.

Coverage and Reimbursement

Our ability to successfully commercialize any approved product candidates will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such treatments. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

The IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the HHS that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions. Although the IRA exempts orphan drugs that treat only one rare disease from the drug pricing negotiation provisions, we do not know if additional drug pricing reforms could eliminate this exemption and therefore affect the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability. The effect of IRA on our business and the pharmaceutical industry in general is not yet known.

Future efforts to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities relating to our product candidates, if approved, and affect our ability to successfully commercialize our product candidates, if approved, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

There have been significant ongoing judicial, administrative, executive and legislative efforts by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Affordable Care Act was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Several healthcare reform proposals culminated in the enactment of the IRA in August 2022, which will eliminate, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Among other things, the IRA also requires HHS to negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products began in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations and has since announced the negotiated maximum fair prices for these drugs. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will represent a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of prescription drug products.

We expect that the Affordable Care Act, the IRA, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our product candidates, if approved.

Foreign Regulatory Requirements

We may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacturing, product registration and approval, pharmaceutical sales and data protection. Whether or not FDA approval has been obtained, we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Facilities

Our principal executive office is located in Wayne, Pennsylvania, where we lease 3,379 square feet of space that we use for our administrative, research and development and other activities. We believe that our existing facilities are adequate for our near-term needs, but expect to need additional space as we grow. We believe that suitable additional or alternative space would be available as required in the future on commercially reasonable terms.

Employees and Human Capital Resources

As of December 20, 2024, we had nine full-time employees, of which one has a Ph.D. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table lists the names, ages and positions of our executive officers and directors:

Name	Age	Position
Executive Officers:		
Wesley H. Kaupinen	47	Chief Executive Officer, President and Director
Matthew Korenberg	49	Chief Financial Officer
Kathleen Goin	54	Chief Operating Officer
Jeffrey Martini Ph.D.	47	Chief Scientific Officer
Non-Employee Directors:		
George M. Jenkins (1)	72	Chairman of the Board
Todd C. Davis (2) (3)	63	Director
Christopher Kiritsy (1)(3)	59	Director
Tadd S. Wessel (2)(3)	48	Director
Elaine J. Heron, Ph.D. (1)(3)	77	Director

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(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

Wesley H. Kaupinen has served as our Chief Executive Officer and as a member of the our board of directors (the "Board") since December 2024.Mr. Kaupinen was previously Chief Executive Officer, President, and a member of the Board of Directors of Legacy Palvella from December 2015 to December 2024. Prior to founding the Company, Mr. Kaupinen served as Senior Vice President, Corporate Development and Commercialization at Insmed, Inc., a publicly traded commercial stage biopharmaceutical company focused on developing novel therapies to treat serious rare diseases, from 2013 to August 2015. Previously, Mr. Kaupinen was a Principal at Quaker Partners, an investment firm focused on public market and venture capital investments in innovative life sciences companies, and an associate in the healthcare group at Apax Partners, a global private equity firm. Mr. Kaupinen is a member of the board of directors of Primrose Bio, a private equity-backed company focused on developing and licensing its manufacturing technologies for nucleic acids and proteins used in therapeutics and vaccines. Mr. Kaupinen previously served on the board of directors of Biocoat (acquired by GTCR), Intact Vascular (acquired by Philips), and TELA Bio (NASDAQ: TELA). Earlier in his career, Mr. Kaupinen also held commercial and general management positions at Synthes (now a part of Johnson & Johnson) and Johnson & Johnson Cordis Cardiology. Mr. Kaupinen earned an M.B.A. from The Wharton School of the University of Pennsylvania and a B.A. in Economics from the University of Virginia.

The Company believes Mr. Kaupinen is qualified to serve on our Board because of his knowledge of the our business, as well as his extensive leadership experience and successful record of commercial operations and product pipeline development.

Matthew Korenberg has served as our Chief Financial Officer since December 2024. Mr. Korenberg was the Chief Financial Officer of Legacy Palvella from October 2024 to December 2024. Prior to joining the Company, Mr. Korenberg served as President and Chief Operating Officer of Ligand Pharmaceuticals Inc. from November 2022 to October 2024 and as Chief Financial Officer from August 2015 to October 2022. Before his tenure at Ligand Pharmaceuticals Inc., Mr. Korenberg was the founder, Chief Executive Officer, and a director of NeuroCircuit Therapeutics, a company focused on developing drugs to treat genetic disorders of the brain with an initial focus on Down syndrome, from September 2013. Earlier in his career, Mr. Korenberg was a Managing Director and member of the healthcare investment banking team at Goldman Sachs from July 1999 through August 2013, where he advised and financed companies in the biotechnology and pharmaceutical sectors across New York, London, and San Francisco. Prior to Goldman Sachs, Mr. Korenberg was a healthcare investment banker at Dillon, Read & Co. Inc., working with healthcare and industrial companies.

Mr. Korenberg is also a member of the board of directors and serves on the audit committee of Lifecore Biomedical, Inc., a publicly traded company in the contract development and manufacturing business, since August 2024. Mr. Korenberg holds a B.B.A. in Finance and Accounting from the University of Michigan.

Kathleen Goin has served as our Chief Operating Officer since December 2024. Ms. Goin was the Vice President, Development Operations of Legacy Palvella from October 2019 to December 2024. From February 2017 to October 2019, Ms. Goin served as Vice President of Clinical Operations at Clinical Works, a MyClin company, a specialty consulting firm focused on helping companies start their clinical programs and execute trials. Prior to that, Ms. Goin served as Vice President, Clinical Operations of Trevena, Inc., a publicly held biotechnology company, from November 2013 to February 2017. Ms. Goin holds a Master of Science in Occupational Therapy from Misericordia University and a B.S. in Political Science from Rosemont College.

Jeffrey Martini, Ph.D., has served as our Chief Scientific Officer since December 2024. Dr. Martini was previously the Chief Scientific Officer of Legacy Palvella from October 2024 to December 2024, and the Senior Vice President, Research and Development and Scientific Affairs from August 2020 to October 2024. Prior to joining the Company, Dr. Martini served in various capacities, including as Executive Director, Business Development and Corporate Strategy and as Executive Director, Program Management, at Marinus Pharmaceuticals, Inc. from July 2018 to August 2020. He also served as Senior Director, Project Champion at Teva Pharmaceuticals Industries Limited from July 2013 to July 2018. Dr. Martini holds a Ph.D. in Molecular Pharmacology and Structural Biology from Jefferson University and a B.S. in Life Sciences from Pennsylvania State University.

Non-Employee Directors

George M. Jenkins has served as a member and Chair of the Board since December 2024. From 1987 until 2005, Mr. Jenkins was a general partner of Apax Partners, a global private equity firm where he served as chief operating officer. Mr. Jenkins currently serves as a board member of several private companies, including Conventus Orthopaedics, Inc. He has previously served on the board of various public and private companies, including SkinMedica (acquired by Allergan plc), Colorescience, Sunglass Hut and Spyder Active Sports. Mr. Jenkins holds an M.B.A. from Pace University and a B.A. in Economics from Lafayette College, where he currently serves as a Trustee Emeritus.

We believe that Mr. Jenkins is qualified to serve on the Board because of his extensive experience in healthcare investment management as well as his executive leadership and directorship experience.

Todd C. Davis has served as a member of the Board since December 2024. Mr. Davis has served as the Executive Chairman of Benuvia Holdings, Inc. since November 2019. He is the founder and managing partner of RoyaltyRx Capital, LLC, a special opportunities investment firm founded in September 2018. From 2006 until January 2018, Mr. Davis was a Co-founder and Managing Partner of Cowen/HealthCare Royalty Partners, a global healthcare investment firm. Previously, Mr. Davis was a Partner at Paul Capital Partners, where he co-managed that firm's royalty investments as a member of the Royalty Management Committee from 2004 to 2006. He also served as a Partner responsible for biopharmaceutical growth equity investments at Apax Partners from 2001 to 2004. Mr. Davis began his business career in various sales and product management roles at Abbott Laboratories where he held several commercial roles of increasing responsibility during the period from 1990 to 1995. He subsequently held general management, business development, and licensing roles at Elan Pharmaceuticals from 1997 to 2001. He currently serves as Chief Executive Officer of Ligand and currently serves on the boards of Ligand, a publicly held biopharmaceutical company, BioDelivery Sciences International, Inc., a publicly held specialty pharmaceutical company, Vaxart, Inc., a publicly held biotechnology company, and Virocell Biologics, where he has served since 2007, 2018, 2019, and 2021, respectively. Mr. Davis holds an M.B.A. from Harvard University and a B.S. from the U.S. Naval Academy.

We believe that Mr. Davis is qualified to serve on the Board because of his extensive experience in the healthcare industry and healthcare investment management as well as his experience as a director of a publicly held biopharmaceutical company.

Christopher Kiritsy has served as a member of the Board since September 2016. Mr. Kiritsy is founder and managing member of Precision Kapital, LLC, a private investment and advisory firm. Prior to forming Precision Kapital, Mr. Kiritsy co-founded Arisaph Pharmaceuticals, Inc., or Arisaph, and served as Arisaph's President and Chief Executive Officer from 2005 through March 2018. At Arisaph, Mr. Kiritsy oversaw the development of a broad preclinical and clinical pipeline, taking several cardiometabolic products into clinical development. Additionally, Mr. Kiritsy employed a unique, shareholder friendly financing strategy, raising nearly two thirds of all capital nondilutively through royalty monetization and grant funding. Prior to Arisaph, Mr. Kiritsy served as Executive Vice President, Corporate Development and Chief Financial Officer of Kos Pharmaceuticals, Inc., or Kos, responsible for finance, corporate communications, strategic planning, and business development functions. During his decade long tenure, Mr. Kiritsy raised approximately $500 million in public equity capital, including Kos' IPO, and spearheaded 10 major corporate development transactions, including product acquisitions, in/out licensing and co-promotion arrangements. Mr. Kiritsy played central role in building Kos from a start-up into publicly traded, profitable, 1,000 person fully-integrated company, where Kos internally developed and commercialized the blockbuster Niaspan® franchise. Kos was acquired by Abbott Laboratories for $4 billion in 2006. Mr. Kiritsy previously served on the board of directors of HTG Molecular Diagnostics, Inc. In addition, Mr. Kiritsy previously served as a board member and audit committee chair of Melinta Pharmaceuticals, Inc., as a board member of Arisaph and as chairman of the board of Avaxia Biologics, Inc. Mr. Kiritsy received his A.B. in Biology from Bowdoin College and his M.B.A. at night from Boston University School of Business. Mr. Kiritsy is a seasoned entrepreneur, possessing 30 years of unique business and technical experience, and a track record of building successful fully integrated biopharma businesses.

We believe that Mr. Kiritsy is qualified to serve on the Board based on his considerable experience in the pharmaceutical industry and his expertise in finance and corporate development.

Tadd S. Wessel has served as a member of the Board since December 2024. Mr. Wessel is the founder and Managing Partner of Petrichor, a private investment firm focused on the healthcare sector. He is also a founder and Managing Partner of Scion Life Sciences, an affiliate of Petrichor. Tadd has more than 25 years of experience, primarily focused on investing and building companies in the life sciences sectors. Previously, he was a Partner at OrbiMed Advisors where he led the build-out of the structured investment business. Prior to OrbiMed, Tadd was a Vice President at Fortress Investment Group focused on healthcare investments. Tadd began his career in the life sciences investment banking groups at Citigroup and Robertson Stephens. Tadd has served on more than 30 boards most recently including Aurion Biotech and ITM Isotope Technologies Munich SE. He also serves on the Advisory Board of the AIM at Melanoma Foundation, whose mission is dedicated to finding more effective treatments and, ultimately, the cure for melanoma. He also serves on the Board of the International Centers for Precision Oncology (ICPO) whose mission is to scale access of molecularly targeted precision oncology diagnostics and therapeutics for the benefit of cancer patients globally. Tadd holds an AB in biology from Princeton University.

We believe that Mr. Wessel is qualified to serve on our the Board based on his extensive experience in the healthcare and finance industries.

Elaine J. Heron, Ph.D. has served as a member of the Board since December 2024. From February 2009 to October 2015, Dr. Heron served as Chair and CEO of Amplyx Pharmaceuticals, Inc., a private drug development company acquired by Pfizer, Inc. in April 2021. Dr. Heron currently serves on the boards of Vaxart, Inc., a public clinical-stage biotechnology company, BioMarin Pharmaceutical Inc**.**, a public global biotechnology company, Visgenx, Inc., a private early-stage therapeutics company, Watershed Medical, Inc., a private early-stage therapeutics company, and BlueWhale Bio, Inc., a private preclinical biotechnology company. Dr. Heron is also an advisor to Kyto Technology and Life Science, Inc. and Cairn Biosciences, Inc. From July 2001 to October 2008, Dr. Heron was Chair and CEO of Labcyte Inc., a private biotechnology company. Before joining Labcyte Inc., Dr. Heron spent six years in positions of increasing responsibility at the Applied Biosystems Group of Applera Corporation, a biotechnology company, including the position of General Manager and Vice President of Sales and Marketing. Dr. Heron earned a B.S. in chemistry with highest distinction and a Ph.D. in analytical biochemistry from Purdue University and an M.B.A. from Pepperdine University.

We believe that Dr. Heron is well qualified to serve on the Board because of her extensive experience in life science sales and marketing, finance and accounting, corporate governance matters and research and development.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, the Board.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Involvement in Certain Legal Proceedings

There are no material legal proceedings to which any of our executive officers is a party adverse to the Company or the Company's subsidiaries or in which any such person has a material interest adverse to the Company or the Company's subsidiaries.

Corporate Governance

Composition of Our Board of Directors

Our Board currently consists of six directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term.

In accordance with the terms of our amended and restated articles of incorporation (as amended the "Articles of Incorporation"), our Board is divided into three classes, Class I, Class II and Class III, with one class of directors being elected in each year and each class serving a three-year term. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. The Board is divided among the following classes:

- Class I, which consists of Wesley H. Kaupinen and Christopher Kiritsy, whose terms will expire at the annual meeting of stockholders to be held in 2027;
- Class II, which consists of Tadd S. Wessel and Elaine J. Heron, whose terms will expire at the annual meeting of stockholders to be held in 2025; and
- Class III, which consists of George M. Jenkins and Todd C. Davis, whose terms will expire at the annual meeting of stockholders to be held in 2026.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election and until their successors are duly elected and qualified, or their earlier resignation, removal, retirement or death. This classification of the Board may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 80% of our voting stock.

Independence of Our Board of Directors

Other than Mr. Kaupinen, our president and chief executive officer, all members of the Board are independent, and all members of committees of the Board are independent. To determine independence, the Board reviewed all relevant identified transactions or relationships between each director, or any of such director's family members, and us, our senior management, and our independent auditors. Our Board has affirmatively determined that the following four current directors are independent directors within the meaning of the applicable Nasdaq listing standards: George M. Jenkins, Todd C. Davis, Tadd S. Wessel, Christopher Kiritsy, and Elaine J. Heron. In making this determination, our Board found that none of these directors or nominees for director had a material or other disqualifying relationship with us. Mr. Kaupinen was determined as not being independent by virtue of his executive leadership role with us.

Accordingly, a majority of our directors are independent, as required under applicable Nasdaq rules. In making this determination, our Board considered the applicable Nasdaq rules and the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including their beneficial ownership of our share capital.

Committees of the Board of Directors

The standing committees of our Board are the following: audit committee, compensation committee and nominating and corporate governance committee, and each operates pursuant to a charter. Our Board may establish other committees from time to time to assist us and our Board.

Audit Committee

The members of our audit committee are George M. Jenkins, Elaine J. Heron, and Christopher Kiritsy, each of whom qualifies as an independent director for audit committee purposes, as defined under the rules of the SEC and the applicable Nasdaq listing rules and has sufficient knowledge in financial and auditing matters to serve on our audit committee. Mr. Jenkins is the chair the audit committee. Mr. Kiritsy is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose any duties, obligations or liabilities that are greater than those generally imposed on members of our audit committee and the Board.

Our audit committee is directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit the combined company's consolidated financial statements and overseeing the retention, compensation, evaluation and, when appropriate, termination of such independent registered public accounting firm;
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results and related disclosures as well as critical accounting policies and practices used by us;
- monitoring and reviewing legal, regulatory, and administrative compliance to the extent affecting our financial results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- determining and reviewing risk assessment guidelines and policies, including cybersecurity risks, financial risk exposure, and internal controls regarding information security;
- preparing and approving the audit committee report required to be included in our annual proxy statement;
- reviewing material related party transactions or those that require disclosure; and
- reviewing quarterly and year-end earnings releases.

Compensation Committee

The members of our compensation committee are Todd C. Davis and Tadd S. Wessel, each of whom qualifies as an independent director, as defined under applicable Nasdaq listing rules and also meets the additional, heightened independence criteria applicable to members of the compensation committee. Mr. Davis is the chair of the compensation committee.

Our compensation committee is responsible for, among other things:

- reviewing and making recommendations to the Board as to our general compensation philosophy and overseeing the development and implementation of an executive compensation program and policies related to such program;
- annually reviewing and recommending to the Board the corporate performance goals and objectives relevant to the compensation of our Chief Executive Officer, and annually reviewing the performance of our Chief Executive Officer and recommending to the Board the compensation level for our Chief Executive Officer;
- annually reviewing and recommending to the Board the corporate performance goals and objectives relevant to the compensation of our other executive officers, and annually reviewing the performance of our other executive officers and recommending to the Board the compensation level for our other executive officers;

- reviewing and recommending to the Board the compensation of our directors;
- overseeing the administration of our stock and equity incentive plans;
- reviewing and approving, or making recommendations to the Board with respect to, incentive compensation and equity plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters; and
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules.

Nominating and Corporate Governance Committee

The members of the our nominating and corporate governance committee are Todd C. Davis, Christopher Kiritsy, Tadd S. Wessel, and Elaine J. Heron, each of whom qualifies as an independent director, as defined under applicable Nasdaq listing rules. Dr. Heron is the chair the nominating and corporate governance committee.

Our nominating and corporate governance committee is responsible for, among other things:

- developing criteria for the selection of new directors and committee membership, including policies regarding the desired knowledge, experience, skills, independence, diversity, and other characteristics of board and committee members;
- identifying, reviewing and evaluating candidates for membership on the Board, including candidates submitted by our stockholders, and making recommendations to the Board regarding nominees to fill vacancies or new positions on the Board and the slate of nominees to stand for election by our stockholders at each annual meeting of stockholders;
- considering proposals submitted by our stockholders and establishing any policies, requirements, criteria and procedures to facilitate stockholder communications with the Board;
- annually reviewing and recommending to the Board determinations with respect to the independence of continuing and prospective directors within the meaning prescribed by the SEC and Nasdaq;
- annually reviewing and recommending to the Board (i) the assignment of directors to serve on each of the Board committees, (ii) the chair of each committee and (iii) the chair of the Board or lead independent director, as appropriate, and recommending additional committee members to fill vacancies or as otherwise needed;
- reviewing all resignations tended by directors and recommending to the Board the action, if any, to be taken with respect to such resignation;
- developing, recommending and overseeing the implementation of our corporate governance guidelines and a code of business conduct and ethics;
- overseeing compliance with and reviewing proposed waivers of the corporate governance guidelines or the code of business conduct and ethics for directors, executive officers and other senior financial officers, and reporting on such compliance to the Board;
- overseeing the process of evaluating the performance of the Board and our committees; and
- assisting the Board on corporate governance matters.

Background and Experience of Directors; Board Diversity

When considering whether directors and nominees have the experience, qualifications, attributes or skills, taken as a whole, to enable the Board to satisfy its oversight responsibilities effectively in light of our business and structure, the Board focused primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

Although the Board has not adopted a specific policy regarding diversity in identifying director nominees, both the nominating and corporate governance committee and the Board seek the talents and backgrounds that would be most helpful to us in selecting director nominees. In particular, our nominating and corporate governance committee, when recommending director candidates to the Board for nomination, may consider whether a director candidate, if elected, assists in achieving a mix of board of directors members that represent a diversity of background and experience.

Code of Business Conduct and Ethics

Following the completion of the Merger, we adopted a written code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics covers fundamental ethics and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of the combined company's property and information, reporting of illegal or unethical behavior, competition and fair dealing and compliance with legal and regulatory requirements. A current copy of our code of business conduct and ethics is posted on the investor relations section of our website. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

Compensation Committee Interlocks and Insider Participation

Each member of the compensation committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of our executive officers serve as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serves on the Board or compensation committee following the completion of the Merger.

Non-Employee Director Compensation

Prior to the Merger, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our Board or committees of our Board. In connection with closing of the Merger, the Board adopted a non-employee director compensation policy designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors and align our directors' interests with those of our stockholders. Employee directors do not receive additional compensation for their services as directors. Under the policy, each non-employee director will receive cash consideration for board service of $40,000 per year with an additional $25,000 in cash consideration for the non-executive chair of the Board. Such directors will receive an additional annual cash consideration for service as the chair of the audit committee, compensation committee and nominating and corporate governance committee of the Board in the amount of $15,000, $10,000 and $8,000, respectively, and an annual cash consideration for service as a member of the audit committee, compensation committee and nominating and corporate governance committee of the Board in the amount of $7,500, $5,000 and $4,000, respectively. Each new non-employee director, upon the commencement of their director service, will receive an initial grant of 24,700 options to purchase our common stock for his or her service on the Board. We will also reimburse its non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending the Board and committee meetings.

EXECUTIVE AND DIRECTOR COMPENSATION

Unless the context otherwise requires, any reference in this section of this prospectus to "Legacy Palvella" refers to Palvella Therapeutics, Inc., a Delaware corporation and its consolidated subsidiaries prior to the consummation of the Merger and any reference to "the Company," "we," or "us" refers to Palvella Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiaries after the Merger. Immediately prior to the effective time of the Merger, all of the executive officers of Pieris resigned and all of the executive officers of Legacy Palvella became our executive officers.

Executive Compensation

This section provides information regarding the total compensation awarded to, earned by, or paid to during the years ended December 31, 2024 and 2023 to (1) each individual who served as our principal executive officer, (2) our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2024 and were serving as executive officers as of such date, and (3) up to two individuals who would otherwise be included in (2) above but for the fact that such individual was not serving as our executive officer as of December 31, 2024. We refer to these individuals in this proxy statement as our named executive officers ("NEOs").

- Wesley H. Kaupinen, President and Chief Executive Officer;
- Kathleen Goin, Chief Operating Officer;
- Jeffrey Martini, Ph.D., Chief Scientific Officer;
- Stephen S. Yoder, Ph.D., former Chief Executive Officer of Pieris;
- Thomas Bures, former Chief Financial Officer of Pieris; and
- Shane Olwill, former Senior Vice President and Chief Development Officer of Pieris.

2024 Summary Compensation Table

The following table sets forth information concerning the compensation of our NEOs for the year ended December 31, 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation	All Other Compensation ($)(3)	Total ($)
Wesley H. Kaupinen							
President and Chief Executive Officer	2024	$ 384,923	$ 228,000	$ 4,534,999	-	$ 643	$ 5,148,564
	2023	$ 375,462	$ -	$ 209,858	-	$ 643	$ 585,963
Kathleen Goin							
Chief Operating Officer	2024	$ 381,440	$ 65,000	$ 485,612	-	$ -	$ 932.052
	2023	$ 354,975	$ 49,056	$ 941,776	-	$ -	$ 1,345,807
Jeffrey Martini, Ph.D.							
Chief Scientific Officer	2024	$ 320,755	$ 53,000	$ 1,336,328	-	$ -	$ 1,710,083
	2023	$ 293,588	$ 39,852	$ 281,539	-	$ -	$ 614,979
Stephen S. Yoder, Ph.D.							
Former Chief Executive Officer of Pieris	2024	$ 535,504	$ -	$ -	-	$ 890,700	$ 1,426,204
	2023	$ 584,595	$ 146,149	$ 614,818	-	$ 13,390	$ 1,358,952
Thomas Bures							
Former Chief Financial Officer of Pieris	2024	$ 383,482	$ -	$ -	-	$ 560,217	$ 943,699
	2023	$ 400,155	$ 80,031	$ 241,536	-	$ 7,315	$ 729,037
Shane Olwill							
Former Senior Vice President and Chief Development Officer of Pieris	2024	$ 262,993	$ -	$ -		$ 434,930	$ 697,923
	2023	$ 328,614	$ 127,702	$ 241,536	-	$ 7,593	$ 705,445

(1) Amounts shown are cash incentive payments earned in respect of 2024 or 2023 performance, as the case may be, and paid in 2024. Our compensation committee has not yet made determinations for discretionary bonuses based on 2024 performance to be paid in 2025.

(2) The amounts reported represent the aggregate grant date fair value of stock options awarded to the NEOs during the 2024 and 2023 fiscal years, calculated in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in (i) Note 2 to each of the financial statements of Pieris and Legacy Palvella for the years ended December 31, 2023, as applicable; and (ii) Note 2 to the unaudited financial statements of Legacy Palvella for the nine months ended September 30, 2024, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and does not correspond to the actual economic value that may be received upon exercise of the stock options or any sale of any of the underlying shares of common stock.

(3) Other compensation reflects the Company's contribution to life insurance and company matching 401(k) contributions. For Dr. Yoder, Mr. Bures, and Mr. Olwill this amount also includes separation payments pursuant to each person's employment agreement of $876,900, $560,217 and $434,930, respectively.

Narrative Disclosure to the Summary Compensation Table 2024

Elements of Compensation

The compensation of our NEOs generally consists of base salary, annual cash bonus opportunities, and other benefits, as described below.

2024 Base Salaries

Our board of directors and compensation committee recognize the importance of base salary as an element of compensation that helps to attract and retain the named executive officers. We provide a base salary as a fixed source of income for our named executive officers for the services they provide to us during the year, which allows us to maintain a stable executive team.

The base salaries for our named executive officers in effect for the year ended December 31, 2024 were as follows: $575,000 for Mr. Kaupinen, $481,300 for Ms. Goin, and $391,700 for Dr. Martini. Dr. Yoder and Mr. Bures terminated their employment immediately prior to the closing of the Merger. Dr. Olwill departed Pieris on October 31, 2024.

Annual Cash Bonus Opportunities

We also provide our NEOs with annual performance-based cash bonus opportunities, calculated based upon the achievement of specified corporate goals, with each executive officer being assigned a corporate and individual goal weighting. For fiscal year 2024, each executive officer was assigned a target bonus opportunity, which is reflected as a percentage of that individual's 2024 base salary and is based on the individual's role and title at the Company.

The 2024 annual bonus opportunity for Mr. Kaupinen, Ms. Goin and Dr. Martini were targeted at 50%, 40% and 40% of their respective base salaries.

Our compensation committee will review performance and approve, or recommend to our board of directors, as applicable, bonus payments to the NEOs in the first quarter of 2025. Bonuses with respect to 2024 performance will be pro-rated for any partial year of employment and are expected to be paid, as applicable, during the first quarter of 2025.

Equity Compensation

We grant stock options and restricted stock to our employees from time to time. Typically, equity awards granted upon an individual's commencement of employment vest 25% upon the first anniversary of the individual's start date, and monthly over 36 months thereafter, subject to continued employment. Subsequent grants generally vest monthly over 48 months, contingent on continued employment. In 2024, Legacy Palvella granted option awards to Legacy Palvella's NEOs, Mr. Kaupinen of 81,459, Ms. Goin of 29,787, and Dr. Martini of 19,888. Upon completion of the Merger, we granted option awards to our NEOs, Mr. Kaupinen of 417,806, Ms. Goin of 27,843, and Dr. Martini of 126,416.

Other Elements of Compensation

As described in the "*All Other Compensation*" column in the "*— 2024 Summary Compensation Table*" above, we made contributions to life insurance and company matching 401(k) contributions and other benefits for the NEOs. For Dr. Yoder, Mr. Bures, and Mr. Olwill this amount also includes separation payment pursuant to each person's employment agreement of $876,900, $560,217 and $434,930, respectively.

Legacy Palvella did not maintain any retirement plans or nonqualified deferred compensation plans. From time to time, Pieris provided its NEOs with employee benefits that its board of directors believed were reasonable. Pieris' NEOs were eligible to participate in the same broad-based employee benefit plans that are offered to Pieris' other employees, such as health insurance, disability insurance, life insurance and a 401(k) plan.

Clawback Policy

We have adopted an incentive compensation recoupment policy that is applicable to our executive officers, and such other of our senior executives as may be determined by our compensation committee. If we determine that we must restate our financial results as reported in a periodic or other report filed with the SEC to correct an accounting error due to material noncompliance with any financial reporting requirement under the U.S. securities laws, we will seek to recover or require forfeiture, at the direction of the compensation committee, after it has reviewed the facts and circumstances that led to the requirement of the restatement and the costs and benefits of seeking recovery, any excess incentive based compensation, received by an officer covered by the policy during the three completed fiscal years immediately preceding the date on which we are required to prepare the accounting restatement. Furthermore, we will seek to recoup incentive compensation that is used in such a way that violates our insider trading policy, for example, by engaging in transactions involving hedging devices or our securities that are used to secure a margin or other loan.

Named Executive Officer Arrangements

Wesley H. Kaupinen

Legacy Palvella entered into an employment agreement with Mr. Kaupinen, dated May 20, 2020 (the "Kaupinen Employment Agreement"), providing for his position as President and Chief Executive Officer and an annual base salary of $350,000. Under the Kaupinen Employment Agreement, Mr. Kaupinen is eligible to receive an annual bonus. In 2021, Legacy Palvella's compensation committee set Mr. Kaupinen's annual bonus target at up to 40% of Mr. Kaupinen's annual base salary, based on the achievement of corporate performance objectives established by Legacy Palvella's compensation committee. Under the Kaupinen Employment Agreement, Mr. Kaupinen is eligible to participate in Legacy Palvella's employee benefit plans, subject to the eligibility requirements of those plans.

The Kaupinen Employment Agreement provides for an indefinite term and is terminable (i) at will by Legacy Palvella or by Mr. Kaupinen, provided that 30 days' advance notice must be provided by the terminating party in the event of a termination of employment without "cause" by Legacy Palvella or Mr. Kaupinen's resignation without "good reason"; (ii) on the date that Mr. Kaupinen provides Legacy Palvella with written notice that he is terminating his employment for good reason (subject to any applicable cure period); and (iii) on the date of his death or on the date of his disability, as reasonably determined by Legacy Palvella.

Under the Kaupinen Employment Mr. Kaupinen is entitled to certain benefits upon termination of employment as described below in the section entitled "*—Termination Payments*."

Kathleen Goin

Ms. Goin is party to an offer letter, dated August 19, 2019 (the "Goin Offer Letter"), that provides for at-will employment and provides for an initial base salary of $300,000 for full-time work commencing in 2020. Under the Goin Offer Letter, Ms. Goin is eligible to receive an annual cash incentive award opportunity under Legacy Palvella's bonus plan. In addition, in connection with her commencement of employment, Ms. Goin received two option awards to purchase, in the aggregate, 83,291 shares of Legacy Palvella common stock, with each option award vesting in accordance with Legacy Palvella's standard vesting schedule for new hire grants. Ms. Goin is eligible to participate in Legacy Palvella's employee benefits plans that are generally made available by Legacy Palvella to its employees, subject to the eligibility requirements of those plans.

Jeffrey Martini, Ph.D.

Dr. Martini is party to an offer letter, dated July 27, 2020 (the "Martini Offer Letter"), that provides for at-will employment and provides for an initial base salary of $275,000. Under the Martini Offer Letter, Dr. Martini is eligible to receive an annual cash incentive award opportunity under Legacy Palvella's bonus plan targeted at 30% of base salary. Dr. Martini was also eligible for a one-time payment of $43,925 related to the achievement of his 2020 Legacy Palvella Goals and Objectives. In addition, in connection with his commencement of employment, Dr. Martini received an option award to purchase 104,283 shares of Legacy Palvella common stock, which vests in accordance with Legacy Palvella's standard vesting schedule for new hire grants. Dr. Martini is eligible to participate in Legacy Palvella's employee benefits plans that are generally made available by Legacy Palvella to its employees, subject to the eligibility requirements of those plans.

Stephen S. Yoder

Dr. Yoder served as Pieris' President and Chief Executive Officer pursuant to the Yoder Employment Agreement, which provided for a continuous term and may be terminated by either party at any time, provided that if Dr. Yoder resigns, he shall provide Pieris with at least 90 days' prior written notice. Dr. Yoder was eligible to receive an annual bonus of up to 50% of his annual base salary based upon achievement of individual and corporate performance objectives as determined by Pieris's Compensation and Management Development Committee in its sole discretion. Dr. Yoder's annual base salary for 2024 is $584,595 (as set by Pieris's Compensation and Management Development Committee in 2023).

Pursuant to his employment agreement, Dr. Yoder was prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chairman of the Pieris board of directors, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Dr. Yoder to be adverse or antagonistic to Pieris, Pieris' business or prospects, financial or otherwise, or in any competing business.

Dr. Yoder's employment agreement also contained (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions extending during the term of the agreement and one year thereafter, and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Dr. Yoder also agreed to assign certain intellectual property rights to Pieris.

In connection with the closing of the Merger Dr. Yoder's employment as President and Chief Executive Officer of the Company terminated.

Thomas Bures

Thomas Bures served as Pieris' Senior Vice President and Chief Financial Officer and was employed at will pursuant to the Bures Employment Agreement. Mr. Bures was eligible to receive an annual bonus of up to 40% of his annual base salary based upon achievement of individual and corporate performance objectives as determined by Pieris's Compensation and Management Development Committee in its sole discretion. Mr. Bures' annual base salary for 2024 was $400,155 (as set by Pieris's Compensation and Management Development Committee in 2023).

Pursuant to his employment agreement, Mr. Bures was prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Mr. Bures to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

Mr. Bures also signed agreements that include (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions extending during the term of the agreement and one year thereafter, and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Mr. Bures also agreed to assign certain intellectual property rights to Pieris.

In connection with the Merger, on the Closing Date, Thomas Bures' employment as Senior Vice President and Chief Financial Officer of the Company terminated. On December 13, 2024, the Company and Mr. Bures entered into a consulting agreement (the "Consulting Agreement") pursuant to which Mr. Bures will provide consulting services related to accounting and reporting matters though the Merger transition on an as needed basis. Mr. Bures will be paid an hourly rate of $500 per hour and will be reimbursed for miscellaneous business and travel-related expenses, if preapproved and incurred while providing services to the Company during the term of the Consulting Agreement. The Consulting Agreement will terminate upon the earlier of (i) the completion of agreed upon services to the satisfaction of Company, or at any time upon 10 days' written notification to Mr. Bures.

Shane Olwill

Shane Olwill served as Pieris' Senior Vice President and Chief Development Officer, and was employed pursuant to an employment contract effective June 15, 2011, and with a continuous term, and could be terminated by either party provided that a statutory notice period is observed in accordance with German law. Dr. Olwill was eligible to receive a bonus of up to 40% of his annual base salary based upon achievement of individual and corporate performance objectives as determined by Pieris's Compensation and Management Development Committee in its sole discretion. Dr. Olwill's annual base salary for 2024 was €304,501 (as set by Pieris's Compensation and Management Development Committee in 2023), which was approximately $262,993 through October 31, 2024 using an assumed 2024 exchange rate of 1.041 U.S. dollars per euro.

Pursuant to his employment agreement, Dr. Olwill was prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) engaging in any paid external activities that would impair Dr. Olwill from performing his duties or unpaid side-line activities that would be competitive with or capable of being competitive with Pieris' business, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Dr. Olwill to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

Dr. Olwill's employment agreement also included customary confidentiality obligations which were not limited by the term of the agreement. Dr. Olwill also agreed to assign certain intellectual property rights to Pieris.

Pieris and Dr. Olwill mutually agreed that in connection with the signing of the Merger Agreement, Dr. Olwill would step down effective October 31, 2024. Pieris and Dr. Olwill entered into a separation agreement, dated as of July 23, 2024, which provided that Dr. Olwill is entitled to a lump sum payment of €417,800, and was released from the obligation to work between August 1, 2024 and October 31, 2024 during which continued to receive his fixed salary. Dr. Olwill departed Pieris effective October 31, 2024.

Confidentiality, Non-Competition, Non-Solicitation and Inventions Agreements

Mr. Kaupinen, Ms. Goin and Dr. Martini each entered into a Confidentiality, Assignment of Inventions, and Restrictive Covenant Agreement (the "Restrictive Covenant Agreements") with Legacy Palvella that includes customary prohibitions against competition with Legacy Palvella and solicitation of Legacy Palvella's customers and employees, both during employment and for the 12-month following any cessation of employment. The Restrictive Covenant Agreements also include standard provisions relating to Legacy Palvella's intellectual property rights and prohibiting the executive from disclosing confidential information.

Payment of any severance benefits under each Legacy Palvella NEO's agreement is conditioned on continued compliance with such Legacy Palvella NEO's Restrictive Covenant Agreement.

Termination Payments

The following describes any termination or "change of control" payments to which the NEOs were entitled pursuant to their employment with the Company:

Wesley H. Kaupinen

Pursuant to the Kaupinen Employment Agreement, upon termination of employment by Legacy Palvella without "cause" or by Mr. Kaupinen for "good reason", Legacy Palvella will provide Mr. Kaupinen with 12 months of salary continuation. Payment of Mr. Kaupinen's severance is conditioned on (i) Mr. Kaupinen's execution of a general release of claims in favor of Legacy Palvella and its affiliates; (ii) Mr. Kaupinen's continued compliance with the provisions of his Restrictive Covenant Agreement; and (iii) Legacy Palvella being financially solvent at the time any such severance payment becomes due, and that the payment of any such severance amounts would not cause Legacy Palvella to become insolvent.

Under the Kaupinen Employment Agreement, "cause" generally means any of the following: (i) indictment, commission of, or other entry of a plea of guilty or no contest to, (A) a felony or (B) any crime (other than a felony) that causes Legacy Palvella or its affiliates public disgrace or disrepute, or adversely affects Legacy Palvella or its affiliates' operations or financial performance or the relationship Legacy Palvella has with its affiliates, customers and suppliers; (ii) commission of an act of gross negligence, willful misconduct, fraud, embezzlement, theft or material dishonesty with respect to Legacy Palvella or any of its affiliates; (iii) a breach of Mr. Kaupinen's fiduciary duties to Legacy Palvella or any of its affiliates; (iv) alcohol abuse or use of controlled substances (other than prescription drugs taken in accordance with a physician's prescription); (v) material breach of any agreement with Legacy Palvella or any of its affiliates, including the Kaupinen Employment Agreement and his Restrictive Covenant Agreement; (vi) a material breach of any of Legacy Palvella's policies regarding employment practices; or (vii) refusal to perform or repeated failure to perform, the lawful directives of the Legacy Palvella board of directors, if not cured within 15 days following his receipt of Legacy Palvella's written notice.

Under the Kaupinen Employment Agreement, "good reason" generally means Mr. Kaupinen's resignation for any of the following reasons, provided he provides notice to Legacy Palvella within 90 days of the initial occurrence of the event, Legacy Palvella fails to cure the issue within 30 days, and he resigns within 30 days of the end of the cure period: (i) a material reduction in his title, duties, authority or responsibilities, provided that such reduction would not be deemed to have occurred if, following a change of control, (A) Legacy Palvella remains a separate entity, and he remains the most senior executive directly responsible for Legacy Palvella's operations, or (B) if Legacy Palvella does not remain a separate entity, and he is the most senior executive directly responsible for the operations of the acquiring entity; (ii) a material breach of the Kaupinen Employment Agreement by Legacy Palvella; (iii) a material reduction in his base salary paid by Legacy Palvella to which he has not provided written consent, other than a decrease in which Legacy Palvella contemporaneously decrease the salaries of all of its senior executives; or (iv) a change of more than 50 miles in the geographic location at which he performs his services.

Under the Kaupinen Employment Agreement, if payments and benefits payable to Mr. Kaupinen in connection with a change in control constitute "excess parachute payments" under Section 280G of the Code, then such payments and benefits will be reduced to the minimum extent necessary so that no portion thereof will fail to be tax-deductible by Palvella or its affiliates under Section 280G of the Code.

Kathleen Goin

Legacy Palvella entered into a severance agreement with Ms. Goin, dated May 22, 2020 (the "Goin Severance Agreement"). The Goin Severance Agreement provides that upon termination of employment by Legacy Palvella without "cause," Legacy Palvella will provide Ms. Goin with three months of salary continuation. Payment of Ms. Goin's severance is conditioned on (i) Ms. Goin's execution of a general release of claims in favor of Legacy Palvella and its affiliates; (ii) Ms. Goin's continued compliance with the provisions of her Restrictive Covenant Agreement; and (iii) Legacy Palvella being financially solvent at the time any such severance payment becomes due, and that the payment of any such severance amounts would not cause Legacy Palvella to become insolvent.

Under the Goin Severance Agreement, "cause" generally has the same meaning as such term has in the Kaupinen Employment Agreement.

Stephen Yoder, Ph.D.

In connection with the closing of the Merger, Stephen Yoder's employment as President and Chief Executive Officer of the Company terminated. Pursuant to the terms of the separation agreement entered into with Dr. Yoder (the "Yoder Separation Agreement"), Dr. Yoder was entitled to receive cash severance in a single lump sum in an amount equal to 12 months of his base salary plus his full target bonus (equivalent to $876,900), as well as 100% acceleration of vesting of all of his outstanding Company equity awards. Subject to Dr. Yoder's election of COBRA, Dr. Yoder is eligible for payment or reimbursement for the employer portion of premiums for Dr. Yoder and his eligible dependents for 12 months. The Yoder Separation Agreement contains a release of claims against the Company, as well as certain ongoing confidentiality and restrictive covenant obligations.

Thomas Bures

In connection with the closing of the Merger, Thomas Bures' employment as Senior Vice President and Chief Financial Officer of the Company terminated. Pursuant to the terms of the separation agreement entered into with Mr. Bures (the "Bures Separation Agreement"), Mr. Bures was entitled to receive cash severance in a single lump sum in an amount equal to the sum of 12 months of his base salary plus his full target bonus (equivalent to $560,217), as well as 100% acceleration of vesting of all of his outstanding Company equity awards. Subject to Mr. Bures' election of COBRA, Mr. Bures is eligible for payment or reimbursement for the employer portion of premiums for Mr. Bures and his eligible dependents for 12 months. The Bures Separation Agreement contains a release of claims against the Company, as well as certain ongoing confidentiality and restrictive covenant obligations.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each NEO as of December 31, 2024.

	Option Awards					Stock Awards	
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price**	**Option Expiration Date**	**Number of Shares of Stock That Have Not Vested**	**Market Value of Shares of Stock That Have Not Vested**
Wesley H. Kaupinen	2/23/2023	9,824 (1)	11,609	$9.79	2/22/2033	—	—
Wesley H. Kaupinen	5/28/2024	15,274 (2)	66,185	$7.53	5/27/2034	—	—
Wesley H. Kaupinen	12/13/2024	- (6)	417,806	$13.60	12/12/2034	-	-
Kathleen Goin	10/30/2019	11,857 (3)	-	$7.14	10/29/2029	—	—
Kathleen Goin	10/30/2019	14,002 (3)	-	$7.14	10/29/2029	—	—
Kathleen Goin	10/15/2020	25,776 (4)	--	$9.08	10/14/2030	—	—
Kathleen Goin	2/23/2023	39,405 (1)	46,569	$9.79	2/22/2033	—	—
Kathleen Goin	2/23/2023	4,681 (1)	5,532	$9.79	2/22/2033	—	—
Kathleen Goin	5/28/2024	5,585 (2)	24,202	$7.53	5/27/2034	—	—
Kathleen Goin	12/13/2024	- (6)	27,843	$13.60	12/12/2034	-	-
Jeffrey Martini, Ph.D.	10/12/2020	32,272 (5)	-	$9.08	10/11/2030	—	—
Jeffrey Martini, Ph.D.	2/23/2023	8,498 (1)	4,681	$9.79	2/22/2033	—	—
Jeffrey Martini, Ph.D.	2/23/2023	4,681 (1)	5,532	$9.79	2/22/2033	—	—
Jeffrey Martini, Ph.D.	5/28/2024	3,729(2)	16,159	$7.53	5/27/2034	—	—
Jeffrey Martini, Ph.D.	12/13/2024	- (6)	126,416	$13,60	12/12/2034	—	—

(1) This option was granted on February 23, 2023 and vests in 48 substantially equal monthly installments. Vesting of the award requires continued employment through the applicable vesting dates.

(2) This option was granted on May 28, 2024 and vests in 48 substantially equal monthly installments. Vesting of the award requires continued employment through the applicable vesting dates.

(3) This option was granted on October 30, 2019, and vests as follows: 25% of the option shares vested on October 30, 2020, and the remaining 75% of the option shares vest in 36 substantially equal monthly installments thereafter. Vesting of the award requires continued employment through the applicable vesting dates.

(4) This option was granted on October 15, 2020, and vests in 48 substantially equal monthly installments. Vesting of the award requires continued employment through the applicable vesting dates.

(5) This option was granted on October 12, 2020, and vests as follows: 25% of the option shares vested on October 12, 2021, and the remaining 75% of the option shares vest in 36 substantially equal monthly installments thereafter. Vesting of the award requires continued employment through the applicable vesting dates.

(6) This option was granted on December 13, 2024, and vests in 48 substantially equal monthly installments. Vesting of the award requires continued employment through the applicable vesting dates.

Equity Compensation Plans

2024 Equity Incentive Plan

Our Board adopted the 2024 Equity Incentive Plan (the "2024 Plan") in connection with and effective as of the closing of the Merger. The following summary does not contain all of the terms and conditions of the 2024 Plan and is qualified in its entirety by reference to the 2024 Plan included as an exhibit to the registration statement of which this prospectus forms a part.

The principal provisions of the 2024 Equity Incentive Plan are summarized below. This summary is qualified in its entirety by reference to the 2024 Equity Incentive Plan document, a copy of which has been filed with the SEC with this prospectus. To the extent the description below differs from the text of the 2024 Equity Incentive Plan, the text of the 2024 Equity Incentive Plan will control.

Administration

The 2024 Equity Incentive Plan vests broad powers in a committee to administer and interpret the Plan. Our Board designated the compensation committee to administer the 2024 Equity Incentive Plan. Except when limited by the terms of the 2024 Equity Incentive Plan, the compensation committee has the authority to, among other things: select the persons to be granted awards; determine the type, size and term of awards; establish performance objectives and conditions for earning awards; and determine whether such performance objectives and conditions have been met. Subject to the requirements of applicable law and our governing documents, the compensation committee may delegate its authority, including its authority to grant awards, under the 2024 Equity Incentive Plan to one or more individuals or another committee. Our Board may at any time exercise the rights and duties of the compensation committee under the 2024 Equity Incentive Plan; accordingly, references herein to the compensation committee will also include the Board.

Our Board may amend, alter or discontinue the 2024 Equity Incentive Plan and the compensation committee may amend any outstanding award at any time; provided, however, that no such amendment or termination may adversely affect awards then outstanding without the holder's permission. In addition, any amendments seeking to increase the total number of shares reserved for issuance under the 2024 Equity Incentive Plan or modifying the classes of participants eligible to receive awards under the Plan will require ratification by our stockholders in accordance with applicable law.

Eligibility

Our employees, directors, consultants, and other service providers, or those of our affiliates, are eligible to participate in the 2024 Equity Incentive Plan and may be selected by the compensation committee to receive an award. However, in accordance with applicable tax rules, only our employees (and the employees of our parent or subsidiary corporations) are eligible to be granted incentive stock options.

Vesting

The compensation committee determines the vesting conditions for awards. A time-based condition requires that the participant be employed or otherwise in the service of us and our affiliates for a certain amount of time in order for the award to vest. A performance-based condition requires that certain performance criteria be achieved in order for the award to vest. Awards may also vest in connection with a participant's termination of employment or in connection with a Change in Control (as described and defined below).

Shares of Stock Available for Issuance

Subject to certain adjustments, the maximum number of shares of our common stock (referred to in this proposal as "common stock" or "shares") that may be issued under the 2024 Equity Incentive Plan is the sum of: (i) 3,340,639 shares, minus (ii) the number of shares subject to Prior Plan awards granted between September 12, 2024 and the Effective Date, plus (iii) up to 115,294 additional shares underlying awards outstanding under the Prior Plan that expire, terminate are canceled or forfeited without issuance to the holder thereof of the full number of shares to which the award related, or the "Share Pool".

If any award granted under the 2024 Equity Incentive Plan or Prior Plan expires, terminates, is canceled or is forfeited, the shares underlying the award will be available for new grants under the 2024 Equity Incentive Plan. Any shares that are withheld for the payment of taxes or in satisfaction of the exercise price an award, will again become available for grant under the 2024 Equity Incentive Plan.

Any shares issued in respect of awards granted in substitution for equity-based awards of an entity acquired by the us or a subsidiary, or with which we or a subsidiary combine, will not reduce the Share Pool.

The maximum aggregate number of shares under the 2024 Equity Incentive Plan that may be issued in respect of incentive stock options is 10,367,799.

In the event of any merger, consolidation, reorganization, recapitalization, stock split, reverse stock split, split up, spin-off, combination of shares, exchange of shares, stock dividend, dividend in kind, or other like change in capital structure (other than ordinary cash dividends) to our stockholders, or other similar corporate event or transaction that affects our common stock, the compensation committee shall make appropriate adjustments in the number and kind of shares authorized by the 2024 Equity Incentive Plan and covered under outstanding awards as it determines appropriate and equitable.

Types of Awards

The 2024 Equity Incentive Plan provides for the grant of the following equity-based and cash-based incentive awards to participants: (i) stock options, (ii) stock appreciation rights, (iii) restricted stock, (iv) restricted stock units, or "RSUs", and (v) other cash or stock-based awards.

Stock Options. A stock option entitles the holder to purchase from us a stated number of our shares at a specified price for a limited period of time. The compensation committee will specify the number of shares of common stock subject to each option and the exercise price for such option, provided that, in case of an ISO, the exercise price may not be less than the fair market value of a share of common stock on the date the option is granted. However, for an ISO granted to a 10% stockholder, the exercise price shall not be less than 110% of the fair market value of common stock on the date the option is granted.

Generally, options may be exercised in whole or in part through a cash payment. The compensation committee, however, may in its discretion permit payment of the exercise price by other methods. For example, unless the compensation committee decides otherwise, the option holder may pay the exercise price of an option through the surrender of previously acquired shares or may "net settle" an option (which involves the cancellation of a portion of the option to cover the cost of exercising the balance of the option).

All options shall be exercisable in accordance with the terms of the applicable award agreement. The maximum term of an option shall be determined by the compensation committee on the date of grant. In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of common stock with respect to which such ISOs become exercisable for the first time during any calendar year cannot exceed $100,000. ISOs granted in excess of this limitation will be treated as non-qualified stock options.

Stock Appreciation Rights. A stock appreciation right represents the right to receive, upon exercise, any appreciation in a share of common stock over a particular time period. The base price of a stock appreciation right shall not be less than the fair market value of the underlying our common stock on the date the stock appreciation right is granted. The maximum term of a stock appreciation right shall be determined by the compensation committee on the date of grant but shall not exceed 10 years. Stock appreciation right payouts may be made in cash, shares of common stock, or a combination of both, at the compensation committee's discretion.

Unless otherwise provided in an award agreement or determined by the compensation committee, if a participant's service with us (or our affiliates) terminates due to death or disability, the participant's unexercised options and stock appreciation rights may be exercised, to the extent they were exercisable at the time of the participant's death or disability (or on such accelerated basis as the compensation committee may determine at or after grant), for a period of twelve months from the termination date or until the expiration of the original award term, whichever period is shorter. If a participant's service with us (or our affiliates) is terminated for cause (as defined in the 2024 Equity Incentive Plan), (i) all unexercised options and stock appreciation rights (whether vested or unvested) shall terminate and be forfeited on the termination date, and (ii) any option or stock appreciation right exercise then in progress will be cancelled.

Unless otherwise provided in an award agreement or determined by the compensation committee, if a participant's service terminates for any other reason, the participant's unexercised options and stock appreciation rights may be exercised, to the extent they were exercisable at the time of the participant's termination (or on such accelerated basis as the compensation committee may determine at or after grant), for a period of ninety days from the termination date or until the expiration of the original option or stock appreciation right term, whichever period is shorter. Unless otherwise provided by the compensation committee, any options and stock appreciation rights that are not exercisable at the time of the termination of service shall terminate and be forfeited on the termination date.

Restricted Stock. A restricted stock award is a grant of shares of common stock that are subject to forfeiture and transfer restrictions during a specified period. The compensation committee will determine the price, if any, to be paid by the participant for each share of restricted stock. If the specified vesting conditions are not attained, the underlying our common stock will be forfeited to us. Conversely, if and when the vesting conditions are satisfied, the restrictions imposed will lapse. During the restriction period, a participant will have the right to vote the shares underlying the restricted stock and receive dividends with respect to restricted stock. However, unless otherwise determined by the compensation committee, any such dividends will be subject to the same vesting conditions as the restricted stock to which they relate. The compensation committee may also require that the dividends be reinvested in additional restricted shares. The compensation committee may issue a certificate or certificates representing the number of shares subject to an award of restricted stock or placed shares in a restricted stock account with the transfer agent during the restriction period. As a condition to any award of restricted stock, a participant may be required to deliver to us a share power, endorsed in blank, relating to the shares of common stock covered an award. Unless otherwise provided in an award agreement or determined by the compensation committee, upon termination of service a participant will forfeit all restricted stock that then remains subject to forfeiture.

Restricted Stock Units. An RSU represents a right to receive, on the achievement of specified vesting conditions, an amount equal to the fair market value of one share of our common stock. An RSU may be settled in shares of our common stock, cash or a combination of both, at the discretion of the compensation committee. Unless otherwise provided in an award agreement or determined by the compensation committee, upon a termination of service, a participant will forfeit all of the participant's RSUs that then remain subject to forfeiture.

Cash and Other Stock-Based Awards. Cash and other stock-based awards (including awards to receive unrestricted shares of our common stock) may be granted to participants. The compensation committee will determine the terms and conditions of each such award, including, as applicable, the term, any exercise or purchase price, vesting conditions and other terms and conditions.

Change in Control

In the event of a change in control (as defined in the 2024 Equity Incentive Plan), the compensation committee may, on a participant-by-participant basis: (i) cause any or all outstanding awards to become vested and immediately exercisable (as applicable), in whole or in part; (ii) cause any outstanding option or stock appreciation right to become exercisable for a reasonable period in advance of the change in control and, to the extent not exercised prior to that change in control, cancel that option or stock appreciation right upon closing of the change in control; (iii) cancel any unvested award or unvested portion thereof, with or without consideration; (iv) cancel any Award in exchange for a substitute award; (v) redeem any restricted stock or restricted stock unit for cash and/or other substitute consideration with value equal to the fair market value of an unrestricted share on the date of the change in control; (vi) cancel any outstanding option or stock appreciation right with respect to all common stock for which the award remains unexercised in exchange for a cash payment equal to the excess (if any) of the fair market value of the common stock subject to the option or stock appreciation right over the exercise price of the option or stock appreciation right; (vii) take such other action as the compensation committee determines to be appropriate under the circumstances; and/or (viii) in the case of any award subject to Section 409A of the Code, the compensation committee shall only be permitted to use discretion to the extent that such discretion would be consistent with the intended treatment of such award under Section 409A of the Code.

Repricing Prohibited

Neither our Board nor the compensation committee may, without obtaining prior approval of our stockholders: (i) implement any cancellation/re-grant program pursuant to which outstanding options or stock appreciation rights under the 2024 Equity Incentive Plan are cancelled and new options or stock appreciation rights are granted in replacement with a lower exercise per share; (ii) cancel outstanding options or stock appreciation rights under the 2024 Equity Incentive Plan with an exercise price per share in excess of the then current fair market value per share for consideration payable in our equity securities; or (iii) otherwise directly reduce the exercise price in effect for outstanding options or stock appreciation rights under the 2024 Equity Incentive Plan.

Clawback

Awards under the 2024 Equity Incentive Plan (and any shares subject to the awards) will be subject to rescission, cancellation or recoupment, in whole or in part, or other similar action in accordance with the terms of any company clawback or similar policy or any applicable law related to such actions, as may be in effect from time-to-time.

Non-Employee Director Compensation Limits

Under the 2024 Equity Incentive Plan, the aggregate amount of equity and cash compensation payable to a non-employee director with respect to a fiscal year, whether under the 2024 Equity Incentive Plan or otherwise, for services as a non-employee director, shall not exceed $750,000, provided that such amount shall be $1,000,000 for the fiscal year in which the applicable non-employee director is initially elected or appointed to the our Board. Such non-employee director limit shall not apply to (i) compensation earned by a non-employee director solely in his or her capacity as chairperson of the our Board or lead independent director, (ii) compensation earned with respect to services a non-employee director provides in a capacity other than as a non-employee director, such as an advisor or consultant, and (iii) compensation awarded by the our Board to a non-employee director in extraordinary circumstances, in each case provided that the non-employee director receiving such additional compensation does not participate in the decision to award such compensation.

Miscellaneous

Generally, awards granted under the 2024 Equity Incentive Plan may not be transferred, except by will or intestate succession. However, the compensation committee may in its discretion authorize the gratuitous transfer of awards (other than incentive stock options) to family members of the grantee, partnerships owned by such family members, trusts for the benefit of such family members or other similar estate planning vehicles. Awards under the 2024 Equity Incentive Plan will be subject to withholding for applicable taxes, to the extent required by law, and the compensation committee may authorize the withholding of shares subject to an award to satisfy required tax withholding. Awards under the 2024 Equity Incentive Plan are intended to be exempt from or comply with the requirements of Section 409A of the Code and will be interpreted accordingly. Unless the 2024 Equity Incentive Plan is extended with the approval of our stockholders, the 2024 Equity Incentive Plan will expire on September 12, 2034 (ten years after our Board adopted the 2024 Equity Incentive Plan).

Federal Tax Consequences

The federal income tax consequences of the issuance, exercise and/or settlement of awards under the 2024 Equity Incentive Plan are described below. The following information is only a summary and does not address all aspects of taxation that may be relevant to a particular participant in light of his or her personal circumstances. Participants should consult with their own tax advisors with respect to the tax consequences inherent in the ownership and exercise of the awards and the ownership and disposition of any underlying securities. The summary does not address the effects of other federal taxes (including possible “golden parachute” excise taxes) or taxes imposed under state, local or foreign tax laws. Tax laws are subject to change. Generally, all amounts taxable as ordinary income to participants under the 2024 Equity Incentive Plan in respect of awards are expected to be deductible by us as compensation at the same time the participant recognizes the ordinary income, subject to the limitations of Section 162(m) of the Code. Under Section 162(m), we cannot deduct compensation paid to certain covered employees in excess of $1 million per year.

Nonqualified Stock Options

A participant recognizes no taxable income when a non-qualified stock option is granted. Upon exercise of a non-qualified stock option, a participant will recognize ordinary income equal to the excess of the fair market value of the shares received over the exercise price of the non-qualified stock option. A participant's tax basis in shares of common stock received upon exercise of a non-qualified stock option will generally be equal to the fair market value of those shares on the exercise date, and the participant's holding period for such shares will begin at that time. Upon sale of shares of common stock received upon exercise of a non-qualified stock option, the participant will realize short-term or long-term capital gain or loss, depending on the period the shares are held. The amount of such gain or loss will be equal to the difference between the amount realized in connection with the sale of the shares and the participant's tax basis in such shares.

Incentive Stock Options

A participant recognizes no taxable income when an incentive stock option is granted or exercised. So long as the participant meets the applicable holding period requirements for shares received upon exercise of an incentive stock option (two years from the date of grant and one year from the date of exercise), gain or loss realized by a participant upon sale of the shares received upon exercise will be long-term capital gain or loss, and we will not be entitled to a deduction. If, however, the participant disposes of the shares before meeting the applicable holding period requirements, or a "disqualifying disposition", the participant will then recognize ordinary income. The amount of ordinary income recognized by the participant is limited to the lesser of the gain on such sale and the difference between the fair market value of the shares of common stock on the date of exercise and the option exercise price. Any gain realized in excess of this amount will be treated as short- or long-term capital gain (depending on how long the shares are held). If the option price exceeds the amount realized upon such a disposition, the difference will be short- or long-term capital loss (depending on how long the shares are held). Notwithstanding the above, individuals subject to Alternative Minimum Tax may recognize ordinary income upon exercise of an incentive stock option.

Stock Appreciation Rights

A participant recognizes no taxable income when a stock appreciate right is granted or vests as long as the grant price is at least equal to the fair market value of our common stock on the date of grant and the stock appreciation right has no additional deferral feature. Upon the exercise of a stock appreciate right, a participant will recognize ordinary income equal to the excess of the fair market value of the shares of common stock underlying the stock appreciate right over the grant price of the stock appreciate right. A participant's tax basis in shares of common stock received upon exercise of a stock appreciate right will generally be equal to the fair market value of those shares on the exercise date, and the participant's holding period for such shares will begin at that time. Upon sale of shares of common stock received upon exercise of a stock appreciate right, the participant will realize short-term or long-term capital gain or loss, depending on the period the shares are held. The amount of such gain or loss will be equal to the difference between the amount realized in connection with the sale of the shares and the participant's tax basis in such shares.

Restricted Stock

If a participant receives shares of restricted stock under the 2024 Equity Incentive Plan and does not make the election described in the next paragraph, the participant will recognize no taxable income upon the receipt of the shares. When the forfeiture conditions with respect to the restricted stock lapse, the participant will recognize ordinary income equal to the fair market value of the shares at that time, less any amount paid for the shares. A participant's tax basis in shares of restricted stock will generally be equal to the income recognized when the forfeiture conditions lapse, and the participant's holding period for the shares will begin at that time. Upon sale of the shares, the participant will realize short- or long-term gain or loss, depending on how long the shares are held after the forfeiture conditions lapse. Such gain or loss will be equal to the difference between the amount realized upon the sale of the shares and the participant's tax basis in the shares.

Participants receiving shares of restricted stock may make an election under Section 83(b) of the Code. By making a Section 83(b) election, the participant elects to recognize compensation income when the shares are received rather than at the time the forfeiture conditions lapse. The amount of such compensation income will be equal to the fair market value of the shares upon receipt (valued without regard to the forfeiture conditions and transfer restrictions applicable to the shares), less any amount paid for the shares. By making a Section 83(b) election, the participant will recognize no additional compensation income when the forfeiture conditions lapse. The participant's tax basis in shares with respect to which a Section 83(b) election is made will generally be equal to the income recognized at grant, and the participant's holding period for such shares will begin at that time. Upon sale of the shares, the participant will realize short- or long-term capital gain or loss, depending on the period the shares were held. However, if the shares are forfeited, the participant will not be entitled to claim a deduction with respect to any income tax paid upon making the Section 83(b) election. To make a Section 83(b) election, a participant must file an appropriate form of election with the IRS and with his or her employer, each within 30 days after the shares of restricted stock are issued.

Restricted Stock Units

When shares of common stock or cash with respect to RSU awards are delivered to the participant, the value of the shares or cash is then taxable to the participant as ordinary income.

Other Stock-Based Awards

The taxation of other stock-based awards will depend upon the design of such awards.

New Plan Benefits

The benefits that will be awarded or paid under the 2024 Equity Incentive Plan are currently not determinable. The awards granted under the incentive plan will depend on the Board or the compensation committee's actions and the fair market value of shares at various future dates and the Board or the compensation committee has not determined future awards or who might receive them. As a result, it is not possible to determine the benefits that executive officers and other employees and non-employee directors and consultants will receive if the 2024 Equity Incentive Plan is approved by the stockholders.

2019 Equity Incentive Plan

Legacy Palvella maintained its 2019 Equity Incentive Plan (the "2019 Plan"). The purpose of the 2019 Plan was to enable Legacy Palvella to recruit and retain highly qualified employees, directors, consultants and other service providers and to provide them with an incentive for productivity and the opportunity to share in Legacy Palvella's growth and value. Legacy Palvella provided these incentives through the grant of stock options, SARs, restricted stock and RSUs.

As noted above, Legacy Palvella terminated the 2019 Plan and ceased granting awards thereunder upon the effective 2024 Plan described above. Any outstanding awards under the 2019 Plan continue to be subject to the terms of the 2019 Plan and the applicable award agreements, until such awards are exercised or settled, or until they terminate or expire by their terms.

The material terms of the 2019 Plan are summarized below. These summaries are qualified in their entirety by reference to the actual text of the 2019 Plan, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Eligibility and Administration. Legacy Palvella's employees, directors, consultants, and other service providers were eligible to receive awards as participants under the 2019 Plan. The Legacy Palvella board of directors administered the 2019 Plan, and it was permitted to appoint a committee to perform some or all of its administrative functions thereunder. Directors who were eligible for awards or received awards may vote on any matters affecting the administration of the 2019 Plan or the grant of awards, but no director were permitted to ac upon the grant of an award to himself or herself. The Legacy Palvella board of directors had full authority to make all determinations and interpretations under the 2019 Plan, and the authority to determine award recipients, the numbers and types of awards to be granted, and the provisions of each award, including the period of their exercisability and the vesting schedule applicable to an award, among other powers under the 2019 Plan.

Shares Subject to the Plan. The maximum number of shares that were permitted to be issued in respect of awards under the 2019 Plan was 2,861,768 shares, which consisted of authorized but unissued shares of Legacy Palvella's non-voting common stock. All shares subject to the 2019 Plan were eligible to be granted pursuant to incentive stock option, or ISOs, awards, which were intended to qualify for tax treatment as set forth under Section 422 of the Code.

Share Recycling. If an award under the 2019 Plan expires, terminates, is canceled, forfeited or is settled for cash, any shares subject to such award may, to the extent of such expiration, termination, cancellation, forfeiture or cash settlement, could be used again for new grants under the 2019 Plan. In addition, the delivery of any share withheld in settlement of a tax withholding obligation associated with an award, or in satisfaction of the exercise price payable upon exercise of an option would cause that share to become available for grant again under the 2019 Plan.

Adjustments. In the event of any recapitalization, reclassification, reorganization, merger, consolidation stock split or combination, stock dividend or other similar event or transaction affecting the shares, Legacy Palvella's board of directors were permitted to make equitable substitutions or adjustments to (i) the aggregate number, class and/or issuer of the securities that may be issued under the 2019 Plan, (ii) to the number, class and/or issuer of securities subject to outstanding awards, and (iii) to the exercise price of outstanding options or SARs.

Options. The 2019 Plan provided for the grant of both incentive stock options and non-qualified stock options to purchase shares of Legacy Palvella common stock at a stated exercise price. The exercise price of stock options granted under the 2019 Plan and the term applicable to each option was be determined by Legacy Palvella's board of directors at the time of grant, however the ISO rules imposed certain limitations on the exercise price and maximum term of such grants.

Restricted stock. The 2019 Plan also allowed for the grant or sale of restricted stock. The price, if any, of shares of restricted stock was be determined by the Legacy Palvella board of directors. During the vesting period, a participant had the right to receive any dividends with respect to restricted stock, provided that the plan administrator was permitted to specify that any such dividends were subject to the same vesting schedule as the shares to which they relate.

Stock appreciation rights and restricted stock units. In addition, the 2019 Plan allowed for the grant of SARs and RSUs, with terms as determined by the Legacy Palvella board of directors in accordance with the 2019 Plan. However, as noted above, Legacy Palvella did not grant any SARs or RSUs under the 2019 Plan.

Change of Control. If Legacy Palvella experienced a "change of control" (including certain dissolution, liquidation, asset sale or merger transactions), the Legacy Palvella board of directors would determine how to treat outstanding awards under its 2019 Plan. This included, without limitation: (i) the acceleration of the vesting conditions on outstanding awards, (ii) the cancellation and/or forfeiture of outstanding awards, unless exercised prior to the change in control or assumed, substituted or continued buy the surviving entity, or (iii) the cashout or redemption of outstanding awards. The Palvella board of directors did not need to treat all outstanding awards in an identical manner.

Transferability. Except as otherwise determined by the Legacy Palvella board of directors with respect to a particular award, awards under the 2019 Plan were generally not transferable prior to vesting other than by will or by the laws or descent and distribution.

Plan Amendment and Termination. The Legacy Palvella board of directors were permitted to amend, alter or discontinue the 2019 Plan at any time, provided that no amendment, alteration or discontinuation could be made which would adversely change the terms of an outstanding award, without that participant's consent.

Director Compensation

Following the Effective Time of the Merger, on December 13, 2024, our board of directors considered and adopted a new non-employee director compensation policy, pursuant to which each non-employee director will receive cash consideration for Board service of $40,000 per year with an additional $25,000 in cash consideration for the non-executive chair of the Board. Such directors will receive an additional annual cash consideration for service as the chair of the audit committee, compensation committee and nominating and corporate governance committee of the Board in the amount of $15,000, $10,000 and $8,000, respectively, and an annual cash consideration for service as a member of the audit committee, compensation committee and nominating and corporate governance committee of the Board in the amount of $7,500, $5,000 and $4,000, respectively. Each new non-employee director, upon the commencement of their director service, will receive an initial grant of 24,700 options to purchase the Company's common stock for his or her service on the Board.

Following the Effective Time of the Merger, and pursuant to the Company's non-employee director compensation policy, each non-employee director, consisting of George M. Jenkins, Todd C. Davis, Christopher Kiritsy, Tadd S. Wessel and Elaine J. Heron, received options to purchase 24,700 shares of the Company's common stock with an exercise price of $13.60, which will vest and become exercisable in 36 equal monthly installments through the third anniversary of the grant date. The options will expire on the 10th anniversary of the grant date (or earlier in case of termination of service).

2024 Director Compensation Table

The following table presents the total compensation paid by the Company to each person who served as a non-employee member of our Board of Directors during the fiscal year ended December 31, 2024. See above for more information on the compensation paid to or earned by Mr. Kaupinen as an employee for the year ended December 31, 2024.

Name	Fees Earned or Paid in Cash ($)(1)	Option/Stock Awards ($)(2) (3)	Non-Equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
George M. Jenkins	$ -	$ 318,142	-	-	-	$ 318,142
Todd C. Davis	$ -	$ 318,142	-	-	-	$ 318,142
Christopher Kiritsy	$ 64,698	$ 236,537	-	-	-	$ 301,235
Tadd S. Wessel	$ -	$ 231,844	-	-	-	$ 231,844
Elaine J. Heron, Ph.D	$ -	$ 231,844	-	-	-	$ 231,844
James Geraghty (4)	$ 82,613	-	-	-	-	$ 82,613
Michael Richman (4)	$ 41,132	-	-	-	-	$ 41,132
Ann Barbier, M.D., Ph.D. (4)	$ 40,115	-	-	-	-	$ 40,115
Peter Kiener, D.Phil. (4)	$ 55,515	-	-	-	-	$ 55,515
Matthew L. Sherman (4)	$ 41,882	-	-	-	-	$ 41,882
Maya R. Said, Sc.D. (4)	$ 40,115	-	-	-	-	$ 40,115

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(1) Amounts represent cash compensation for services rendered as a director during 2024.

(2) The amounts reported represent the aggregate grant date fair value of stock options granted to the non-employee directors during fiscal year 2024, calculated in accordance with FASB ASC Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of awards made prior to the Merger by Legacy Palvella reported in this column are set forth in Note 2 to the financial statements of Legacy Palvella for the nine months ended September 30, 2024, included elsewhere in this prospectus. For awards made after the Merger, assumptions used in the calculation of the amounts will be included in a footnote to the Company's audited financial statements for the year ended December 31, 2024. The amounts reported in this column reflect the accounting cost for the stock options and does not correspond to the actual economic value that may be received upon exercise of the stock options or any sale of any of the underlying shares of common stock.

(3) The following table shows the number of outstanding stock options held by our directors as of December 31, 2024:

Name	Number of Shares Underlying Outstanding Options (1)(2)
George M. Jenkins	43,125
Todd C. Davis	40,804
Christopher Kiritsy	28,512
Tadd S. Wessel	24,700
Elaine J. Heron, Ph.D.	29,342

(4) In accordance with the Merger agreement, the director resigned from our board of directors and any board committees on which he or she was a member.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation agreements and other arrangements with us and our directors and executive officers in the section titled "*Pieris Executive and Director Compensation*" and "*Legacy Palvella Executive and Director Compensation*" elsewhere in this prospectus, the following is a description of each transaction involving us, Pieris or Legacy Palvella since January 1, 2022 in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of the average of Legacy Palvella's or our total assets at year-end for the last two completed fiscal years, as applicable; and
- any of our directors, executive officers, or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest

PIPE Financing

On December 13, 2024, we completed the PIPE Financing. Pursuant to the Purchase Agreement, we issued and sold, and the investors purchased, (i) 3,168,048 shares of common stock and (ii) Pre-Funded Warrants, exercisable for 2,466,456 shares of common stock, at a purchase price of $13.9965 per share or $13.9955 per Pre-Funded Warrant, which represents the per share purchase price of the common stock less the $0.001 per share exercise price for each Pre-Funded Warrant, for an aggregate purchase price of approximately $78.9 million, consisting of approximately $60.0 million in cash and the conversion of approximately $18.9 million of principal and interest under outstanding convertible notes issued by Legacy Palvella. The table below sets forth the number of shares of common stock or Pre-Funded Warrants purchased by related parties at the closing of the PIPE Financing.

Participant	Shares of Common Stock	Pre-Funded Warrants	Total Purchase Price
Averill Master Fund, Ltd	714,463		$ 9,999,981
Entities affiliates with BVF Partners	—	1,071,695	$ 14,999,979
Entities affiliated with Samsara BioCapital, LP	35,722	—	$ 499,983
Eagles Mere Air Museum Foundation(1)	11,026	—	$ 154,328
Todd C. Davis	36,732	—	$ 514,126
Wesley H. Kaupinen	1,470		$ 20,577

(1) George M. Jenkins, a member and chair of our board of directors, controls Eagle Mere Air Museum Foundation.
(2) Todd C. Davis is a member of our board of directors.
(3) Wesley H. Kaupinen is our President and Chief Executive Officer and a member of our board of directors.

2024 Registration Rights Agreement

On December 13, 2024, we entered into a registration rights agreement with the PIPE Investors with respect to the Resale Shares (the "Registrable Securities") in the PIPE Financing (the "Registration Rights Agreement") with the selling stockholders named therein, pursuant to which, among other things, we agreed to provide for the registration and resale of the Registerable Securities held by such selling stockholders from time to time.

Legacy Palvella Transactions

The following includes a summary of transactions since January 1, 2021, to which Legacy Palvella had been a party in which the amount involved exceeded the lesser of (i) $120,000 and (ii) 1% of the average of Legacy Palvella's total assets at year-end for the prior two fiscal years, and in which any of Legacy Palvella's directors, executive officers or, to Legacy Palvella's knowledge, beneficial owners of more than 5% of Legacy Palvella capital stock or any member of the immediate family of any of the foregoing persons had or would have had a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "*Executive Compensation.*" Legacy Palvella also describes below certain other transactions with its directors, executive officers and holder of more than 5% of Legacy Palvella capital stock.

Series D Preferred Stock Financing

In December 2022, Legacy Palvella sold an aggregate of 1,835,227 shares of Legacy Palvella's Series D preferred stock at a purchase price of $5.29 per share for aggregate gross cash proceeds of approximately $9.7 million. At the Effective Time, each share of Legacy Palvella's Series D preferred stock converted into the right to receive a number of shares of Palvella common stock (subject to the payment of cash in lieu of fractional shares) calculated in accordance with the exchange ratio set forth in the Merger Agreement.

The following table summarizes the Series D preferred stock purchased by certain members of the Legacy Palvella board of directors or their affiliates and holders of more than 5% of Legacy Palvella's outstanding capital stock. The terms of these purchases were the same for all purchasers of Legacy Palvella's Series D preferred stock. Please refer to the section entitled "*Our Principal Stockholders*" for more details regarding the shares held by certain of these purchasers.

Name of Stockholder	Shares of Series D Preferred Stock		Total Purchase Price
Entities affiliates with Petrichor Healthcare Capital Management (1)	945,555	$	5,000,000
Samsara BioCapital L.P.(2)	189,111	$	1,000,000
Entities affiliates with BVF Partners (3)	94,555	$	499,998
George M. Jenkins(4)	28,367	$	150,002
Wesley H. Kaupinen(5)	17,034	$	90,074
Kathleen A. McGowan (6)	1,127	$	5,959

(1) Consists of (i) 288,300 shares of Series D Preferred Stock held by Petrichor Opportunities Fund I Intermediate LP and (ii) 657,255 shares of Series D Preferred Stock held by Petrichor Opportunities Fund I LP. Tadd S. Wessel, a member of the Legacy Palvella board of directors, is a managing partner of Petrichor Healthcare Capital Management, the investment manager of Petrichor Opportunities Fund I Intermediate LP and Petrichor Opportunities Fund I LP.

(2) Aditya Asokan, Ph.D. a member of the Legacy Palvella board of directors, and is affiliated with Samsara BioCapital GP, LLC.

(3) Consists of (i) 526,075 shares of Series D Preferred Stock held by Biotechnology Value Fund II, L.P., (ii) 50,810 shares of Series D Preferred Stock held by Biotechnology Value Fund L.P., and (iii) 4,471 shares of Series D Preferred Stock held by Biotechnology Value Trading Fund OS, L.P. BVF Partners was a holder of more than 5% of our outstanding capital stock at the time of the consummation of the Series D preferred stock financing.

(4) George Jenkins was a member of the Legacy Palvella board of directors.

(5) Wesley H. Kaupinen was Legacy Palvella's President and Chief Executive Officer and a member of the Legacy Palvella board of directors.

(6) Kathleen A. McGowan was Legacy Palvella's Vice President, Finance and Operations.

Convertible Note Financing

Between June and July 2024, Legacy Palvella issued and sold convertible notes in the aggregate principal amount of $12,433,000. Simple interest accrued on the outstanding principal amount of the convertible notes at an annual rate of SOFR plus 2.0% per annum. Unless earlier converted, the maturity date was the earliest to occur of (i) the date that Legacy Palvella received approval of an NDA by the FDA of the QTORIN rapamycin in the United States, or (ii) the date that is July 3, 2027. Upon the closing of the PIPE Financing, the entire outstanding principal amount and unpaid accrued interest on the convertible notes automatically converted into the common stock of Palvella at the same price per share of the Palvella common stock issued in a PIPE Financing.

The following table summarizes the convertible notes purchased by certain members of the Legacy Palvella board of directors or their affiliates and holders of more than 5% of Legacy Palvella's outstanding capital stock. The terms of these purchases were the same for all purchasers of Legacy Palvella's convertible notes.

Name of Noteholder		Principal Amount of Convertible Notes
Petrichor Opportunities Fund I LP. (1)	$	2,500,000
Ligand Pharmaceuticals Incorporated (2)	$	2,500,000
Todd C. Davis (2)	$	500,000
George M. Jenkins (3)	$	150,000
Wesley H. Kaupinen (4)	$	20,000

(1) Tadd S. Wessel, a former member of the Legacy Palvella board of directors, is a managing partner of Petrichor Healthcare Capital Management, the investment manager of Petrichor Opportunities Fund I LP.

(2) Todd C. Davis was a member of the Legacy Palvella board of directors and the Chief Executive Officer of Ligand Pharmaceuticals Incorporated.

(3) George M. Jenkins was a member of the Legacy Palvella board of directors.

(4) Wesley H. Kaupinen was Legacy Palvella's President and Chief Executive Officer and a member of Legacy Palvella board of directors.

Transactions with Ligand Pharmaceuticals, Inc.

In December 2018, Legacy Palvella entered into the Original Ligand Agreement with Ligand whereby Ligand made a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. In November 2023, Legacy Palvella entered into the Amended Ligand Agreement whereby Ligand made an additional one-time payment of $5.0 million to fund the development of QTORIN rapamycin. Under the Amended Ligand Agreement, Ligand was entitled to receive up to $8.0 million in milestone payments upon the achievement of certain milestones by Legacy Palvella related to QTORIN rapamycin for the treatment of any and all indications, of which $5.0 million of potential future milestone payments remain under the arrangement. In addition, Legacy Palvella agreed to pay to Ligand tiered royalties from 8.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. The Amended Ligand Agreement includes an option for Ligand to purchase additional product revenue participation rights from Legacy Palvella over period of time (as set forth in the Amended Ligand Agreement). The option allows Ligand, for each product developed on the QTORIN platform that completes the first human clinical trial in the United States, the opportunity to make a certain upfront payments to Legacy Palvella in return for a specified royalty rate (as set forth in the Amended Ligand Agreement). Legacy Palvella's obligation to make future milestone payments under the Amended Ligand Agreement was determined to be a derivative liability and Legacy Palvella's obligation to make future royalty payments was determined to be a debt instrument. Todd C. Davis was a member of Legacy Palvella's board of directors and is the Chief Executive Officer of Ligand.

Stock Option Grants to Executive Officers and Directors

Legacy Palvella granted options to its executive officers and certain of its directors as more fully described in the section entitled "*Executive Compensation.*"

Employment Agreements

Employee Agreements

Legacy Palvella entered into employment agreements, offer letters and/or severance agreements with each of its NEOs. See "*Legacy Palvella Executive and Director Compensation—Named Executive Officer Employment Agreements*" for a further discussion of these arrangements.

Policies and Procedures for Related Party Transactions

In connection with the closing of the Merger, we adopted a written related party transaction policy, setting forth the policies and procedures for the review and approval or ratification of related-party transactions. This policy covers any transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we are or will be a participant and a related party has or will have a direct or indirect material interest, as determined by the audit committee of the Board, including, without limitation, purchases of goods or services by or from the related party or entities in which the related party has a material interest, and indebtedness, guarantees of indebtedness or employment by us of a related party.

All related party transactions described in this section occurred prior to adoption of this policy and as such, these transactions were not subject to the approval and review procedures set forth in the policy. However, these transactions were reviewed and approved by the Legacy Palvella board of directors. The Legacy Palvella board of directors reviewed and approved transactions with directors, officers and holders of 5% or more of Legacy Palvella's voting securities and their affiliates, each a related party. Prior to the Merger, the material facts as to the related party's relationship or interest in the transaction are disclosed to the Legacy Palvella board of directors prior to their consideration of such transaction, and the transaction is not considered approved by the Legacy Palvella boards of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when Legacy Palvella stockholders were entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction were disclosed to the stockholders, who must approve the transaction in good faith.

Pieris Transactions and Agreements

Pieris' Audit Committee Charter required the Audit Committee to review, consider, and approve in advance all future transactions, in which Pieris was a participant, that involved amounts that equal or exceed $120,000 and in which any Related Person had or would have had a direct or indirect material interest in such transaction. Related Persons include any of Pieris' directors, executive officers, holder of 5% or more of any class of Pieris capital stock, or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K. In approving or rejecting any such proposal, Pieris' Audit Committee was to consider all available information deemed relevant by the Audit Committee, including, but not limited to, the extent of the related person's interest in the transaction, and whether the transaction was on terms no less favorable to Pieris than terms Pieris could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Related Person Transactions

On July 23, 2024, BVF, which held more than 5% of Pieris' voting securities, along with other PIPE Investors, entered into the Purchase Agreement with Pieris, pursuant to which such PIPE Investors agreed to subscribe for and purchase (either for cash or in exchange for the termination and cancellation of outstanding convertible notes issued by Legacy Palvella), and Pieris agreed to issue and sell to the PIPE Investors, an aggregate of approximately 3,154,241 of shares of Pieris common stock at a price per share equal to the Purchase Price, subject to adjustment as set forth in the Purchase Agreement, and/or in lieu of Pieris common stock to certain purchasers who so chose, Pre-Funded Warrants to purchase up to 2,592,585 shares of the combined company common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price, subject to adjustment as set forth in the Purchase Agreement, minus $0.001. Each of BVF, Samsara Biocapital, L.P., Averill Master Fund, Ltd. and Integrated Finance Group agreed to purchase shares pursuant to the Purchase Agreement and, together with each of their respective affiliates, were expected to be beneficial owners of 5% or more than the outstanding shares of Pieris following the PIPE Financing.

Other than the foregoing, since July 1, 2022, there had not been, nor was there currently proposed, any transaction to which Pieris was a party in which the amount involved exceeds the lesser of $120,000 and 1% of the average of Pieris' total assets at year-end for the last two completed fiscal years, and in which any of Pieris' directors, executive officers, holders of more than 5% of any class of Pieris' voting securities or any of their respective affiliates or immediate family members, had, or would have had, a direct or indirect material interest.

Indemnification Agreements with Directors and Executive Officers

Pieris entered into indemnification agreements with each of its directors and executive officers. Each of those indemnification agreements was in the form approved by the Pieris board of directors. Those indemnification agreements required that, under the circumstances and to the extent provided for therein, Pieris indemnified such persons to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by any such person as a result of such person being made a party to certain actions, suits, and proceedings by reason of the fact that such person was a director, officer, employee, or agent of Pieris, any entity that was a predecessor corporation of Pieris, or any of Pieris' affiliates. The rights of each person who was a party to such an indemnification agreement were, in addition to any other rights such person might have had under applicable Nevada law, Pieris' amended and restated articles of incorporation, Pieris' amended and restated bylaws, any other agreement, a vote of Pieris stockholders, a resolution adopted by the Pieris board of directors, or otherwise.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding beneficial ownership of our common stock as of December 20, 2024:

- each person or group of affiliated persons known to be the beneficial owner of more than 5% of our common stock;
- each of our executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, we believe that the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

The percentage of beneficial ownership is calculated based on 11,221,307 shares of common stock outstanding upon as of December 20, 2024. The number of shares beneficially owned includes shares of common stock that each person has the right to acquire within 60 days of December 20, 2024, including upon the exercise of stock options. These stock options shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock but shall not be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock expected to be owned by any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Palvella Therapeutics, Inc., 125 Strafford Avenue, Suite 360, Wayne, Pennsylvania 19087.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (%)
5% Stockholders:		
Samsara BioCapital (1)	679,486	6.06%
Averill Master Fund, Ltd (2)	714,463	6.37%
Biotechnology Value Fund, L.P. and affiliates (3)	1,168,131	9.99%
Directors and Named Executive Officers:		
Wesley H. Kaupinen (4)	1,644,869	14.61%
Katheen Goin (5)	105,131	*
Jeffrey Martini Ph.D. (6)	53,241	*
Matthew Korenberg	---	*
George M. Jenkins (7)	201,973	1.80%
Todd C. Davis (8)	120,502	1.07%
Tadd S. Wessel(9)	686	*
Christopher Kiritsy (10)	4,248	*
Elaine J. Heron, Ph.D.(11)	56,617	*
All current executive officers and directors as a group (9 individuals)	2,187,267	19.11%

*Less than 1%.

(1) Consists of 679,486 shares common stock held of record by Samsara BioCapital, L.P., or Samsara LP. Samsara BioCapital GP, LLC, or Samsara GP, is the sole general partner of Samsara LP and may be deemed to beneficially own the shares held of record by Samsara LP. Srinivas Kamaraj is a managing member of Samsara GP and may be deemed to beneficially own the shares held of record by Samsara LP. The mailing address of Samsara LP is 628 Middlefield Road, Palo Alto, California 94301.

(2) Consists of 714,463 shares common stock held of record by Averill Master Fund, Ltd., or Averill. Aaron Cowen is the manager of Averill and may be deemed to beneficially own the shares of record held by Averill. The mailing address of Averill is 540 Madison Avenue, 7th Floor, New York, NY 10022.

(3) Biotechnology Value Fund, L.P., or BVF, and its related entities beneficially own 1,168,131 shares of common stock consisting of (i) 371,915 shares of common stock held of record by BVF, (ii) 282,222 shares of common stock held of record by Biotechnology Value Fund II, L.P., or BVF II, (iii) 38,960 shares of common held of record by Biotechnology Value Trading Fund OS, L.P., or Trading Fund OS (iv) 888 shares of common held of record by Investment 10 LLC, or Investment 10, (v) 2,566 shares of common held of record by MSI BVF SPV, LLV, or MSI, (vi) 247,076 pre-funded warrants which are exercisable for shares of common stock to be held of record by BVF, (vii) 196,158 pre-funded warrants which are exercisable for shares of common stock to be held of record by BVF II, (viii) 19,700 pre-funded warrants which are exercisable for shares of common stock to be held of record by Trading Fund OS, and (ix) 8,646 pre-funded warrants which are exercisable for shares of common stock to be held of record by MSI, and excluding (i) 314,418 pre-funded warrants which are exercisable for shares of common stock to be held of record by BVF, (ii) 249,624 pre-funded warrants which are exercisable for shares of common stock to be held of record by BVF II, (iii) 25,070 pre-funded warrants which are exercisable for shares of common stock to be held of record by Trading Fund OS, (iv) 11,003 pre-funded warrants which are exercisable for shares of common stock to be held of record by MSI (v) warrants exercisable for 3,522,000 shares of common stock, (vi) 85 shares of Series A Convertible Preferred Stock held of record by BVF and its related entities, which is convertible into 1,133 shares of common stock, (vii) 4,026 shares of Series B Convertible Preferred Stock held of record by BVF and its related entities, which is convertible into 53,706 shares of common stock, (viii) 3,506 shares of Series C Convertible Preferred Stock held of record by BVF and its related entities, which is convertible into 46,770 shares of common stock, (ix) 3,000 shares of Series D Convertible Preferred Stock held of record by BVF and its related entities, which is convertible into 40,020 shares of common stock, and (x) 5,000 shares of Series E Convertible Preferred Stock held of record by BVF and its related entities, which is convertible into 66,700 shares of common stock. The pre-funded warrants and warrants may not be exercised if, after such exercise, BVF and its affiliates would beneficially own more than 9.99% of the number of shares of common stock then issued and outstanding. As a result of the limitation in the previous sentence, for purposes of the table above, a portion of the shares of common stock issuable upon the exercise of the pre-funded warrants are included and no shares of common stock are included from the warrants. BVF I GP LLC, or BVF GP, as the general partner of BVF, may be deemed to beneficially own the 618,991 shares held of record by BVF. BVF II GP LLC, or BVF II GP, as the general partner of BVF II, may be deemed to beneficially own the 478,380 shares held of record by BVF II. BVF Partners OS Ltd., Partner OS, as the general partner of Trading Fund OS, may be deemed to beneficially own the 58,660 shares held of record by Trading Fund OS. BVF GP Holdings LLC, or BVF GPH, as the sole member of each of BVF GP and BVF II GP, may be deemed to beneficially own the 1,097,371 shares held of record in the aggregate by BVF and BVF II. BVF Partners L.P., or Partners, as the investment manager of BVF and its related entities, and the sole member of Partners OS, may be deemed to beneficially own the 1,168,131 shares held of record in the aggregate by the BVF and its related entities. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 1,168,131 shares beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 1,168,131 shares beneficially owned by BVF Inc. The mailing address of each of the BVF is 44 Montgomery Street, 40th Floor, San Francisco, California 94104.

(4) Consists of (i) 781,409 shares of common stock held of record by Wesley H. Kaupinen 2019 Irrevocable Trust dated February 28, 2019 for the benefit of Wesley H. Kaupinen, (ii) 781,409 shares of common stock held of record by Christine L. Kaupinen 2019 Irrevocable Trust dated February 28, 2019 for the benefit of Wesley H. Kaupinen's spouse, (iii) 44,410 held of record by Wesley H. Kaupinen, and (iv) 37,641 shares of common stock subject to options that are exercisable within 60 days of the Closing Date.

(5) Consists of 105,131 shares of common stock subject to options that are exercisable within 60 days of the Closing Date.

(6) Consists of 53,241 shares of common stock subject to options that are exercisable within 60 days of the Closing Date.

(7) Consists of (i) 180,671 shares of common stock held of record by George M. Jenkins, (ii) 11,026 shares held by Eagles Mere Museum Foundation, an entity which is controlled by Mr. Jenkins, (iii) 10,276 shares of common stock subject to options held by Mr. Jenkins that are exercisable within 60 days of the Closing Date.

(8) Consists of (i) 112,547 shares of common stock held of record by Todd C. Davis, and (ii) 7,955 shares of common stock held by Todd C. Davis subject to options exercisable within 60 days of the Closing Date.

(9) Consists of 686 shares of common stock subject to options exercisable within 60 days of the Closing Date.

(10) Consists of (i) 250 shares of common stock held of record by Christopher Kiritsy, and (ii) 3,998 shares of common stock subject to options exercisable within 60 days of the Closing Date.

(11) Consists of (i) 5,879 shares of common stock held of record by Elaine Jones Heron Trust for the benefit of Elaine J. Heron, Ph.D., (ii) 45,410 held of record by Elaine J. Heron, Ph.D., and (iii) 5,328 shares of common stock subject to options exercisable within 60 days of the Closing Date

SELLING SECURITYHOLDERS

The selling stockholders acquired the Resale Shares from us immediately following the consummation of the Merger (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Legacy Palvella) pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act. Under the Registration Rights Agreement, we agreed to file a registration statement with the SEC for the purposes of registering for resale from time to time the Resale Shares.

The table below lists the selling stockholders and other information regarding their ownership of the shares of common stock offered hereby. The second column lists the number of shares of common stock beneficially owned by the selling stockholders as of December 20, 2024 immediately following consummation of the Merger and the PIPE Financing. The selling stockholders may have sold or transferred some or all of the common stock indicated below and may in the future sell or transfer some or all of the common stock indicated below in transactions exempt from the registration requirements of the Securities Act rather than under this prospectus. The third column lists the shares of common stock being offered by this prospectus by the selling stockholders. The fourth column assumes the sale of all of the shares of common stock offered by the selling stockholders pursuant to this prospectus. The selling stockholders may sell all, some or none of their shares of common stock in this offering. See "*Plan of Distribution*."

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the selling stockholders have sole voting and investment power with respect to all shares of common stock that they own, subject to applicable community property laws. Beneficial ownership for the purposes of the table below is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting thereof, or to dispose or direct the disposition thereof or has the right to acquire such powers within 60 days. Percentage of beneficial ownership is based on 11,221,307 shares of common stock outstanding as of December 20, 2024.

Name and Address of Selling Stockholders	Number of Shares Beneficially Owned Before the Offering	Number of Shares that May Be Offered Hereby	Shares Beneficially Owned After the Offering	
			Number	Percentage
Samsara BioCapital L.P.(1)	679,486	35,722	643,764	5.74%
CDK Associates, LLC(2)	418,667	33,579	385,088	3.43%
Third Street Holdings, LLC(3)	26,723	2,143	24,580	*%
Biotechnology Value Fund, L.P. (4)	1,044,239	561,494	482,745	4.06%
Biotechnology Value Fund II, L.P. (5)	808,699	445,782	362,917	3.09%
Biotechnology Value Trading Fund OS, L.P. (6)	96,511	44,770	51,741	*%
MSI BVF SPV, LLC(7)	26,245	19,649	6,596	*%
Wesley H. Kaupinen(8)	1,644,869	1,470	1,643,399	14.60%
Todd C. Davis(9)	120,502	36,732	83,770	*%
Petrichor Opportunities Fund I LP(10)	331,711	128,311	203,400	1.81%
Petrichor Opportunities Fund I Intermediate LP(11)	145,502	56,283	89,219	*%
Ligand Pharmaceuticals, Inc. (12)	243,119	184,595	58,524	*%
Integrated Finance Group(13)	728,452	728,452	-	-%
Turl Street Ventures LLC(14)	15,148	3,676	11,472	*%
Coy Blevins	59,197	10,511	48,686	*%
BioAdvance Capital, Inc.(15)	231,394	7,350	224,044	2.00%
Michael Christopher(16)	98,259	5,145	93,617	*%
John L. Lewis, IV	38,929	3,676	35,253	*%
Eagles Mere Air Museum Foundation(17)	11,026	11,026	-	-%
Charis Menschel	57,765	11,019	46,746	*%
Gore Range Capital Fund II LLC(18)	80,415	36,523	43,892	*%
Ram Pasture LLC(19)	226,778	51,425	175,353	1.56%
Averill Master Fund, Ltd. (20)	714,463	714,463	-	-%
Nantahala Capital Partners Limited Partnership(21)	53,739	53,739	-	-%
NCP RFM LP(22)	43,209	43,209	-	-%
Blackwell Partners LLC – Series A(23)	153,114	153,114	-	-%
Frazier Life Sciences X, L.P. (24)	8,217	8,217	-	-%
Frazier Life Sciences XI, L.P. (25)	8,574	8,574	-	-%
Frazier Life Sciences Public Fund L.P. (26)	1,366,344	1,366,344	-	-%
Frazier Life Sciences Public Overage Fund L.P. (27)	403,073	403,073	-	-%
Blue Owl Healthcare Opportunities IV Public Investments LP(28)	250,062	250,062	-	-%
DAFNA Lifescience Select LP(29)	20,364	20,364	-	-%
DAFNA Lifescience LP(30)	51,088	51,088	-	-%
ADAR1 Partners, LP(31)	64,007	64,007	-	-%
Spearhead Insurance Solutions IDF, LLC - Series ADAR1(32)	7,445	7,445	-	-%
Concord Biotech Limited(33)	71,472	71,472	-	-%

* Represents beneficial ownership of less than one percent.

(1) Samsara BioCapital GP, LLC (Samsara LLC) is the general partner Samsara BioCapital L.P. Dr. Srinivas Akkaraju, MD, Ph.D. has voting and investment power over the shares held by Samsara LLC. Samsara LLC disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein. The address for above referenced entities and persons is 628 Middlefield Road, Palo Alto, CA 94301.

(2) Caxton Corporation is the manager of CDK Associates, L.L.C., and Bruce Kovner is the chairman and sole shareholder of Caxton Corporation. Each of Caxton Corporation and Bruce Kovner disclaims beneficial ownership of these shares except to the extent of its or his pecuniary interest, if any, therein. The address for above referenced entities and persons is 731 Alexander Road, Building 2, Suite 500, Princeton, NJ 08540.

(3) Caxton Corporation is the manager of Third Street Holdings, LLC, and Bruce Kovner is the chairman and sole shareholder of Caxton Corporation. Each of Caxton Corporation and Bruce Kovner disclaims beneficial ownership of these shares except to the extent of its or his pecuniary interest, if any, therein. The address for above referenced entities and persons is 731 Alexander Road, Building 2, Suite 500, Princeton, NJ 08540.

(4) Consists of (i) 482,745 shares of common stock held by Biotechnology Value Fund, L.P., or BVF, which includes (a) 27,787 shares of common stock issuable upon conversion of 2,083 shares of Series B Convertible Preferred Stock, (b) 23,958 shares of common stock issuable upon conversion of 1,796 shares of Series C Convertible Preferred Stock, (c) 23,465 shares of common stock issuable upon conversion of 1,759 shares of Series D Convertible Preferred Stock, and (d) 35,617 shares of common stock issuable upon conversion of 2,670 shares of Series E Convertible Preferred Stock, and (ii) 561,494 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by BVF. BVF I GP LLC (BVF GP) is the general partner of BVF. BVF GP Holdings LLC (BVF GPH), is the sole member of BVF GP. BVF Partners L.P. (BVF Partners) is investment manager of BVF. BVF Inc. is the general partner of BVF Partners, and Mark N. Lampert, is director and officer of BVF Inc. Each of BVF GP, BVF GPH, BVF Partners, BVF Inc., and Mark N. Lampert disclaims beneficial ownership of securities beneficially owned by BVF. The address for above referenced entities and persons is 44 Montgomery Street, Suite 4000, San Francisco, CA 94104.

(5) Consists of (i) 362,917 shares of common stock held by Biotechnology Value Fund II, L.P., or BVF II, which includes (a) 22,131 shares of common stock issuable upon conversion of 1,659 shares of Series B Convertible Preferred Stock, (b) 19,276 shares of common stock issuable upon conversion of 1,445 shares of Series C Convertible Preferred Stock, (c) 14,380 shares of common stock issuable upon conversion of 1,078 shares of Series D Convertible Preferred Stock, and (d) 24,906 shares of common stock issuable upon conversion of 1,867 shares of Series E Convertible Preferred Stock, and (ii) 445,782 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by BVF II. BVF II GP LLC (BVF II GP) is the general partner of BVF II. BVF GP Holdings LLC (BVF GPH), is the sole member of BVF II GP. BVF Partners L.P. (BVF Partners) is investment manager of BVF II. BVF Inc. is the general partner of BVF Partners, and Mark N. Lampert, is director and officer of BVF Inc. Each of BVF II GP, BVF GPH, BVF Partners, BVF Inc., and Mark N. Lampert disclaims beneficial ownership of securities beneficially owned by BVF II. The address for above referenced entities and persons is 44 Montgomery Street, Suite 4000, San Francisco, CA 94104.

(6) Consists of (i) 51,741 shares of common stock held by Biotechnology Value Trading Fund OS, L.P., or BVF Trading Fund OS which includes (a) 1,133 shares of common stock issuable upon conversion of 85 shares of Series A Convertible Preferred Stock, (b) 3,788 shares of common stock issuable upon conversion of 284 shares of Series B Convertible Preferred Stock, (c) 3,535 shares of common stock issuable upon conversion of 265 shares of Series C Convertible Preferred Stock, (d) 2,174 shares of common stock issuable upon conversion of 163 shares of Series D Convertible Preferred Stock, and (e) 2,147 shares of common stock issuable upon conversion of 161 shares of Series E Convertible Preferred Stock, and (ii) 44,770 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by BVF Trading Fund OS. BVF Partners OS Ltd. (BVF Partners OS) is the general partner of BVF Trading Fund OS. BVF Partners L.P. (BVF Partners), is sole member of BVF Partners OS and investment manager of BVF Trading Fund OS. BVF Inc. is the general partner of BVF Partners, and Mark N. Lampert, is director and officer of BVF Inc. Each of BVF Partners OS, BVF Partners, BVF Inc., and Mark N. Lampert disclaims beneficial ownership of securities beneficially owned by BVF Trading Fund OS. The address for above referenced entities and persons is 44 Montgomery Street, Suite 4000, San Francisco, CA 94104.

(7) Consists of (i) 6,596 shares of common stock held by MSI BVF SPV, LLC, or MSI BVF, which includes 4,028 shares of common stock issuable upon conversion of 302 shares of Series E Convertible Preferred Stock, and (ii) 19,649 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by MSI BVF. BVF Partners L.P. (BVF Partners) is investment manager of MSI BVF. BVF Inc. is the general partner of BVF Partners, and Mark N. Lampert, is director and officer of BVF Inc. Each of BVF Partners, BVF Inc., and Mark N. Lampert disclaims beneficial ownership of securities beneficially owned by MSI BVF. The address for above referenced entities and persons is 44 Montgomery Street, Suite 4000, San Francisco, CA 94104.

(8) Consists of (i) 781,409 shares of common stock held of record by Wesley H. Kaupinen 2019 Irrevocable Trust dated February 28, 2019 for the benefit of Wesley H. Kaupinen, (ii) 781,409 shares of common stock held of record by Christine L. Kaupinen 2019 Irrevocable Trust dated February 28, 2019 for the benefit of Wesley H. Kaupinen's spouse, (iii) 44,410 held of record by Wesley H. Kaupinen, and (iv) 37,641 shares of common stock subject to options that are exercisable within 60 days of December 20, 2024. Mr. Kaupinen is our President, Chief Executive Officer, and a member of our Board. The address for this person is c/o Palvella Therapeutics, Inc., 125 Strafford Ave, Ste 360, Wayne, PA 19087.

(9) Consists of (i) 112,547 shares of common stock held of record by Todd C. Davis, and (ii) 7,955 shares of common stock held by Todd C. Davis subject to options exercisable within 60 days of December 20, 2024. Mr. Davis a member of our Board. The address for this person is c/o Palvella Therapeutics, Inc., 125 Strafford Ave, Ste 360, Wayne, PA 19087.

(10) Tadd Wessel, a member of our Board, is a control person of Petrichor Opportunities Fund I LP and disclaims beneficial ownership of securities beneficially owned by Petrichor Opportunities Fund I LP. The address for above referenced entity is 220 East 42nd Street, 37th Floor, New York, NY 10017.

(11) Tadd Wessel, a member of our Board, is a control person of Petrichor Opportunities Fund I Intermediate LP and disclaims beneficial ownership of securities beneficially owned by Petrichor Opportunities Fund I Intermediate LP. The address for above referenced entity is 220 East 42nd Street, 37th Floor, New York, NY 10017.

(12) Todd Davis is the Chief Executive Officer of Ligand Pharmaceuticals, Inc. and as such may be deemed to beneficially own these shares. Mr. Davis is also a member of our Board. The address for above referenced entity is 555 Heritage Drive, Suite 200, Jupiter, FL 33458.

(13) Mario A. Patone is a control person of Integrated Finance Group and as such may be deemed to beneficially own these shares. The address for above referenced entity is 1055 Westlake Dr., Suite 200, Berwyn, PA 19312.

(14) James Aldige is a control person of Turl Street Ventures LLC and as such may be deemed to beneficially own these shares. The address for above referenced entity is 11 Orchard Road, Charlottesville VA 22903.

(15) Shahram Hejazi is a control person of BioAdvance Capital, Inc. and as such may be deemed to beneficially own these shares. The address for above referenced entity is 101 West Elm Street, Suite 330, Conshohocken, PA 19428.

(16) Consists of (i) 93,617 shares of common stock held of record by Michael Christopher, and (ii) 4,642 shares of common stock held by Michael Christopher subject to options exercisable within 60 days of December 20, 2024. The address for this person is c/o Palvella Therapeutics, Inc., 125 Strafford Ave, Ste 360, Wayne, PA 19087.

(17) George Jenkins is a control person of Eagles Mere Air Museum Foundation and as such may be deemed to beneficially own these shares. Mr. Jenkins is also Chairman of our Board. The address for above referenced entity is c/o Palvella Therapeutics, Inc., 125 Strafford Ave, Ste 360, Wayne, PA 19087.

(18) Gore Range Capital LLC is the manager of Gore Range Capital Fund II LLC. Ethan Rigel is the managing member of Gore Range Capital LLC and as such may be deemed to beneficially own these shares. The address for above referenced entity is 1560 E Southlake Blvd, Southlake, TX 76092.

(19) Ryan Drant is a control person of Ram Pasture LLC and as such may be deemed to beneficially own these shares. The address for above referenced entity is 1156 15th Street NW, Washington, DC 20016.

(20) Suvretta Capital Management, LLC (Suvretta Capital) is the investment manager of Averill Master Fund, Ltd. Aaron Cowen is a control person of Suvretta Capital and as such may be deemed to beneficially own these shares. The address for above referenced entities and persons is 540 Madison Avenue, 7th Floor, New York, NY 10022.

(21) Nantahala Capital Management LLC (Nantahala) is the general partner and/or investment manager of Nantahala Capital Partners Limited Partnership. Nantahala is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address for above referenced entities and persons is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(22) Nantahala Capital Management LLC (Nantahala) is the general partner and/or investment manager of NCP RFM LP. Nantahala is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as Investment Manager and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address for above referenced entities and persons is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(23) Nantahala Capital Management LLC (Nantahala) is the general partner and/or investment manager of Blackwell Partners LLC – Series A. Nantahala is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as Investment Manager and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address for Nantahala referenced entities and persons is 130 Main St., 2nd Floor, New Canaan, CT 06840. The address for Blackwell Partners LLC – Series A is 280 South Mangum Street, Suite 210 Durham, NC 27701.

(24) Consists of (i) 2,576 shares of common stock held by Frazier Life Sciences X, L.P., or FLS X, and (ii) 5,641 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by FLS X. FHMLS X, L.P. is the general partner of FLS X, and FHMLS X, L.L.C. is the general partner of FHMLS X, L.P. James Topper, M.D., Ph.D., and Patrick Heron are the sole managing members of FHMLS X, L.L.C. and share voting and investment power of the securities held by FLS X. Dr. Topper and Mr. Heron disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein. The address for above referenced entities and persons is 1001 Page Mill Rd., Building 4, Ste. B, Palo Alto, CA 94304.

(25) Consists of (i) 2,688 shares of common stock held by Frazier Life Sciences XI, L.P., or FLS XI, and (ii) 5,886 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by FLS XI. FHMLS XI, L.P. is the general partner of FLS XI, and FHMLS XI, L.L.C. is the general partner of FHMLS XI, L.P. James Topper, M.D., Ph.D., Daniel Estes, Ph.D., and Patrick Heron are the sole managing members of FHMLS XI, L.L.C. and share voting and investment power of the securities held by FLS XI. Dr. Topper, Dr. Estes and Mr. Heron disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein. The address for above referenced entities and persons is 1001 Page Mill Rd., Building 4, Ste. B, Palo Alto, CA 94304.

(26) Consists of (i) 428,379 shares of common stock held by Frazier Life Sciences Public Fund, L.P., or FLS Public Fund, and (ii) 937,965 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by FLS Public Fund. FHMLSP, L.P. is the general partner of FLS Public Fund and FHMLSP, L.L.C. is the general partner of FHMLSP, L.P. Albert Cha, James N. Topper, Patrick J. Heron and James Brush are the managing directors of FHMLSP, L.L.C. and therefore share voting and investment power over the shares held by FLS Public Fund. Dr. Cha, Dr. Topper, Mr. Heron and Dr. Brush disclaim beneficial ownership of the shares held by FLS Public Fund except to the extent of their pecuniary interests in such shares, if any. The address for above referenced entities and persons is 1001 Page Mill Rd., Building 4, Ste. B, Palo Alto, CA 94304.

(27) Consists of (i) 126,307 shares of common stock held by Frazier Life Sciences Public Overage Fund, L.P., or FLS Overage Fund, and (ii) 276,766 shares of common stock issuable upon the exercise of Pre-Funded Warrants held by FLS Overage Fund. FHMLSP Overage, L.P., is the general partner of FLS Overage Fund and FHMLSP Overage, L.L.C. is the general partner of FHMLSP Overage, L.P. Dr. Cha, Dr. Topper, Mr. Heron and Dr. Brush are the members of FHMLSP Overage, L.L.C. and therefore share voting and investment power over the shares held by FLS Overage Fund. Dr. Cha, Dr. Topper, Mr. Heron and Dr. Brush disclaim beneficial ownership of the shares held by FLS Overage Fund except to the extent of their pecuniary interests in such shares, if any. The address for above referenced entities and persons is 1001 Page Mill Rd., Building 4, Ste. B, Palo Alto, CA 94304.

(28) Blue Owl Healthcare Opportunities Advisors LLC is the investment manager of Blue Owl Healthcare Opportunities IV Public Investments LP and has voting and investment power over the securities held by Blue Owl Healthcare Opportunities IV Public Investments LP. Blue Owl Healthcare Opportunities Advisors LLC exercises voting and investment power through an investment committee comprised of Kevin Raidy, Timothy Anderson, Sandip Agarwala, and Brandyn Itzkowitz, who each disclaims beneficial ownership over these securities. The address for Blue Owl Healthcare Advisers LLC is c/o 399 Park Avenue, 38th Floor, New York, NY 10022.

(29) DAFNA Capital Management LLC is the sole general partner of DAFNA LifeScience, LP and DAFNA LifeScience Select, LP. The Chief Executive Officer and Chief Investment Officer of DAFNA Capital Management LLC are Dr. Nathan Fischel and Dr. Fariba Ghodsian, respectively. These individuals may be deemed to have shared voting and investment power of the shares held by DAFNA LifeScience, LP and DAFNA LifeScience Select, LP. Each of Dr. Fischel and Dr. Ghodsian disclaim beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The address for above referenced entity is 10990 Wilshire Blvd., Suite 1400, Los Angeles, CA 90024.

(30) DAFNA Capital Management LLC is the sole general partner of DAFNA LifeScience, LP and DAFNA LifeScience Select, LP. The Chief Executive Officer and Chief Investment Officer of DAFNA Capital Management LLC are Dr. Nathan Fischel and Dr. Fariba Ghodsian, respectively. These individuals may be deemed to have shared voting and investment power of the shares held by DAFNA LifeScience, LP and DAFNA LifeScience Select, LP. Each of Dr. Fischel and Dr. Ghodsian disclaim beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The address for above referenced entity is 10990 Wilshire Blvd., Suite 1400, Los Angeles, CA 90024.

(31) Daniel Schneeberger is a control person of ADAR1 Partners, LP and as such may be deemed to beneficially own these shares. The address for ADAR1 Partners, LP is 504 Wild Cherry Drive, Building 9, Austin, TX 78738.

(32) Spearhead IDF Partners is the manager of Spearhead Insurance Solutions IDF, LLC - Series ADAR1. Spearhead IDF Partners is controlled by Ken Foley, as managing member. The address for above referenced entities and persons is 3828 Kennett Pike, Suite 202, Greenville, DE 19807.

(33) The address for this entity is 16th Floor, B-Wing, Mondeal Heights, ISCKON Cross Road, S.G. Highway, Ahmedabad 380015, Gujarat, India.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated articles of incorporation, as amended, and amended and restated bylaws are summaries and are qualified in their entirety by reference to such amended and restated articles of incorporation, as amended, and amended and restated bylaws and applicable provisions of Nevada law, including Chapters 78 and 92A of the NRS. Copies of these documents are filed with the SEC as exhibits to our periodic filings.

General

Our authorized capital stock consists of 200,000,000 shares of our common stock, par value $0.001 per share, and 10,000,000 shares of our preferred stock, par value $0.001 per share, of which authorized our preferred stock 4,963 shares have been designated as Series A Convertible preferred stock, 5,000 shares have been designated as Series B Convertible Preferred Stock, 3,522 shares have been designated as Series C Convertible Preferred Stock, 3,000 shares have been designated as Series D Convertible Preferred Stock, and 5,000 shares have been designated as Series E Convertible Preferred Stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Holders of our common stock are entitled to receive any dividends as may be declared by our board of directors, subject to any preferential dividend or other rights of any then outstanding preferred stock.

Voting Rights

For all matters submitted to a vote of stockholders, each holder of our common stock is entitled to one vote for each share registered in the holder's name on our books. At all meetings of the stockholders, except where otherwise provided by applicable law, rules of any stock exchange upon which our securities are listed, our amended and restated articles of incorporation or our amended and restated bylaws, the presence, in person, virtually or by duly authorized proxy, of the holders of a majority of the outstanding shares of our capital stock entitled to vote constitutes a quorum for the transaction of business. Except as otherwise provided by applicable law or by our amended and restated articles of incorporation or our amended and restated bylaws, all matters, other than the election of directors, proposed at any meeting of the stockholders shall be determined by a majority of the votes cast affirmatively or negatively. Except as otherwise provided by law, our amended and restated articles of incorporation, our amended and restated bylaws or the terms of any class or series of our preferred stock, directors are elected by a plurality of the votes of the shares of our common stock present virtually or by proxy at the meeting and entitled to vote generally on the election of directors.

Dividends

Subject to limitations under Nevada law, any provision of our amended and restated articles of incorporation and any preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared by our board of directors, in their sole discretion, out of legally available funds.

Liquidation

Upon our liquidation, dissolution or winding up, the holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all our debts and other liabilities of the company, subject to any prior rights of any preferred stock then outstanding.

Other Rights and Restrictions

Holders of our common stock do not have preemptive or subscription rights, and they have no right to convert our common stock into any other securities. There is no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of our preferred stock, including any which we may designate in the future. Our amended and restated articles of incorporation and amended and restated bylaws do not restrict the ability of a holder of our common stock to transfer the holder's shares of our common stock.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “PVLA.”

Transfer Agent and Registrar

The transfer agent and registrar for Palvella common stock is Computershare Investor Services, LLC, P.O. Box 43006, Providence, RI 02940-3078, telephone number: 1-877-373-6374.

Preferred Stock

Under the terms of our amended and restated articles of incorporation, the Board is authorized to issue up to 10,000,000 shares of preferred stock in one or more series without stockholder approval by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the NRS. The Board has the discretion to determine the designations, rights, preferences, privileges and restrictions, including voting powers (full, limited or no voting powers), dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The authorization of the Board to issue preferred stock and determine the rights and preferences of that preferred stock eliminates delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Anti-Takeover Effects of Nevada Law and Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws.

Nevada law and our amended and restated articles of incorporation, as amended, and amended and restated bylaws contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of Palvella. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of Palvella to first negotiate with the Board.

Staggered Board; Removal of Directors. Our amended and restated articles of incorporation, as amended, divides the the Board into three classes with staggered three-year terms. In addition, a director may only be removed for cause and only by the affirmative vote of the holders of at least 80% of the votes that all of our stockholders would be entitled to cast in an annual election of directors. Any vacancy or newly-created directorship on the Board may only be filled by vote of a majority of our directors then in office, even though less than a quorum, or by a sole remaining director, and not by stockholders. The classification of the Board and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of Palvella.

No Stockholder Action by Written Consent; Special Meetings. Our amended and restated articles of incorporation, as amended, and amended and restated bylaws provide that any action required or permitted to be taken by Palvella stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our amended and restated articles of incorporation and amended and restated bylaws also provide that, except as otherwise required by law, special meetings of Palvella stockholders can only be called by the Board.

Advance Notice Requirements for Stockholder Proposals. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of Palvella stockholders, including proposed nominations of persons for election to the Board. Stockholders at a Palvella annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a Palvella stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Amendment of Our amended and restated articles of incorporation and amended and restated bylaws. The NRS provides generally that the affirmative vote of a majority of the outstanding shares entitled to vote thereon is required to amend a corporation's articles of incorporation, unless a corporation's articles of incorporation require a greater percentage. Our amended and restated bylaws may be amended or repealed by a majority vote of the Board or by the affirmative vote of the holders of at least 80% of the votes that all Palvella stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 80% of the votes that all Palvella stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our amended and restated articles of incorporation described above under "*—Staggered Board; Removal of Directors*" and "*—No Stockholder Action by Written Consent; Special Meetings*," and under this section " *—Amendment of Our amended and restated articles of incorporation and amended and restated bylaws*."

Acquisitions, Business Combinations and Change in Control The NRS contains provisions governing the acquisition of a controlling interest in certain Nevada corporations. Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elect to restore such voting rights. These laws would apply to us as of a particular date if we were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on our stock ledger at all times during the 90 days immediately preceding that date) and do business in the State of Nevada directly or through an affiliated corporation, unless our amended and restated articles of incorporation or amended and restated bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority, or (3) a majority or more of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares which it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply. Our amended and restated articles of incorporation include a provision stating that these laws, or any successor statutes, relating to acquisitions of controlling interests in Palvella, shall not apply to us or to any acquisition of any shares of our capital stock. These laws may have a chilling effect on certain transactions if our amended and restated articles of incorporation are amended to eliminate the foregoing provision and these laws otherwise apply according to their terms.

Nevada's "combinations with interested stockholders" statutes (NRS 78.411 through 78.444, inclusive) provide that specified types of business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" of the corporation are prohibited for two years after such person first becomes an "interested stockholder" unless the corporation's board of directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or unless the combination is approved by the board of directors and 60% of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates. Furthermore, in the absence of prior approval certain restrictions may apply even after such two-year period. For purposes of these statutes, an "interested stockholder" is any person who is (1) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (2) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between a corporation and an "interested stockholder". These laws generally apply to Nevada corporations with 200 or more stockholders of record. However, a Nevada corporation may elect in its articles of incorporation not to be governed by these particular laws, but if such election is not made in the corporation's original articles of incorporation, the amendment (1) must be approved by the affirmative vote of the holders of stock representing a majority of the outstanding voting power of the corporation not beneficially owned by interested stockholders or their affiliates and associates, and (2) is not effective until 18 months after the vote approving the amendment and does not apply to any combination with a person who first became an interested stockholder on or before the effective date of the amendment. We have not made such an election in our original articles of incorporation, and we have not amended our amended and restated articles of incorporation to so elect.

Further, NRS 78.139 provides that directors may resist a change or potential change in control of the corporation if the board of directors determines that the change or potential change is opposed to or not in the best interest of the corporation upon consideration of any relevant facts, circumstances, contingencies or constituencies pursuant to NRS 78.138(4).

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

Material U.S. Federal Income Tax Consequences for Holders of Common Stock

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock, which we refer to as our securities. This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the Code), including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own 5% or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the securities;
- persons holding the securities as part of a "straddle," hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the Internal Revenue Service, or the IRS, as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of our securities, the U.S. federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

Material U.S. Federal Income Tax Consequences for U.S. Holders

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of our common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under "*U.S. Holders-Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock*" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock. Upon a sale or other taxable disposition of common stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its common stock so disposed of. A U.S. holder's adjusted tax basis in its common stock generally will equal the U.S. holder's acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Material U.S. Federal Income Tax Consequences for Non-U.S. Holders

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, and does not deal with non-U.S., state and local tax consequences that may be relevant to Non-U.S. Holders, nor does it address any U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the U.S. Internal Revenue Code of 1986, as amended, or the Code, such as:

- banks, insurance companies and other financial institutions,
- tax-exempt organizations,
- brokers, dealers and certain electing traders in securities who mark their securities positions to market for U.S. tax purposes,
- certain former U.S. citizens or long-term residents,
- "controlled foreign corporations,"
- "passive foreign investment companies,"
- corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. income taxpayers for U.S. federal tax purposes,
- persons that hold our common stock as part of a "straddle," "conversion transaction," "synthetic security," integrated investment or other risk reduction strategy,
- persons subject to the alternative minimum tax, the federal Medicare contribution tax on net investment income or the special tax accounting rules under Section 451(b) of the Code,
- tax-qualified retirement plans,
- persons who acquire our common stock through the exercise of an option or otherwise as compensation,
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds,
- persons that own or have owned, actually or constructively, more than 5% of our common stock, and
- partnerships and other pass-through entities or arrangements, and investors in such pass-through entities or arrangements.

Such Non-U.S. Holders are urged to consult their tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

In addition, this discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). Furthermore, the discussion below is based upon the provisions of the Code, Treasury regulations promulgated thereunder, rulings and judicial decisions, in each case as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

Persons considering the purchase of our common stock pursuant to this offering should consult their tax advisors concerning the U.S. federal income, estate and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or non-U.S. tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Person, nor a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation). A "U.S. Person" means any person that is, for U.S. federal income tax purposes, any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more "United States persons" (within the meaning of Code Section 7701(a)(30)) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable Treasury regulations to be treated as a United States person.

In the case of a beneficial owner of our common stock that is classified as a partnership for U.S. federal income tax purposes, the tax treatment of a person treated as a partner in such partnership for U.S. federal income tax purposes generally will depend on the status of the partner, the activities of the partner and the partnership and certain determinations made at the partner level. A person treated as a partner in a partnership or who holds our common stock through another pass-through entity should consult his, her or its tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Distributions. Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. federal income tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussions below regarding effectively connected income, backup withholding and foreign accounts. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us or the applicable withholding agent with a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty and, in certain circumstances, providing such Non-U.S. Holder's U.S. taxpayer identification number and/or foreign tax identifying number. This certification must be provided prior to the payment of dividends and must be updated periodically. In the case of a Non-U.S. Holder that is an entity, Treasury regulations and the relevant income tax treaty provide rules to determine whether, for purposes of determining the applicability of an income tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds our common stock through a financial institution or other agent acting on its behalf, it will be required to provide appropriate documentation to such agent, which will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If the Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and does not timely file the required certification, it may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

We and other applicable withholding agents are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that it maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent prior to the payment of such dividends. In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular rates applicable to U.S. Persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder's adjusted basis in our common stock, but not below zero, and then will be treated as capital gain to the extent of any excess, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock. Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless:

(a) the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such Non-U.S. Holder maintains in the United States),

(b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or

(c) we are or have been a "United States real property holding corporation," or USRPHC, within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition and such Non-U.S. Holder's holding period.

In general, we would be a USRPHC if the aggregate fair market value of our "United States real property interests" (within the meaning of Code Section 897(c)(1)), or USRPIs, equaled or exceeded fifty percent (50%) of the combined fair market value of our USRPIs, our non-U.S. real property interests and our other business assets. We believe that we have not been and are not, and do not anticipate becoming, a USRPHC. Even if we are or were to become a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax under the provisions applicable to USRPIs so long as our common stock is "regularly traded," as defined by applicable Treasury regulations, on an established securities market. There can be no assurance that we are not or will not become a USRPHC or that our common stock will qualify as regularly traded on an established securities market.

Non-U.S. Holders described in (a) above will be required to pay tax on the gain derived from the sale or other taxable disposition at regular U.S. federal income tax rates applicable to U.S. Persons, and corporate Non-U.S. Holders described in (a) above may, in addition, be subject to a branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, as adjusted for certain items. A Non-U.S. Holder described in (b) above will be subject to U.S. federal income tax at a flat 30% rate, or such lower rate as may be specified by an applicable income tax treaty, on gain realized upon the sale or other taxable disposition, which gain may be offset by certain U.S.-source capital losses of the Non-U.S. Holder (even though the Non-U.S. Holder is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

Information Reporting Requirements and Backup Withholding. Generally, we or an applicable withholding agent will be required to report information to the IRS with respect to any distributions we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such distributions, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the Non-U.S. Holder to whom any such distributions are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Distributions to a Non-U.S. Holder that are classified as dividends paid by us may also be subject to U.S. backup withholding currently at a rate of 24%. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the applicable payor has actual knowledge, or reason to know, that the Non-U.S. Holder is a U.S. Person who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a sale or other taxable disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise meets documentary evidence requirements for establishing non-U.S. Person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the payor has actual knowledge, or reason to know, that the Non-U.S. Holder is, in fact, a U.S. Person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. payors.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or credit against the U.S. federal income tax liability of a Non-U.S. Holder subject to backup withholding, provided that the required information is timely furnished to the IRS.

Foreign Accounts. Sections 1471 through 1474 of the Code and the related Treasury regulations, together with other U.S. Treasury and IRS guidance issued thereunder and intergovernmental agreements, legislation, rules and other official guidance adopted pursuant to such intergovernmental agreements (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments to a "foreign financial institution" (as defined in the Code) which does not provide the withholding agent with sufficient documentation evidencing either (x) an exemption from FATCA or (y) its compliance (or deemed compliance) with FATCA (which may alternatively be in the form of compliance with an intergovernmental agreement with the United States) to withhold on certain payments and to collect and provide to the U.S. tax authorities certain information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments to a non-financial foreign entity (as defined in the Code) which does not provide the withholding agent with sufficient documentation evidencing either (x) an exemption from FATCA or (y) either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from FATCA. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The withholding provisions described above generally apply to payments of dividends. Under proposed Treasury regulations, the preamble to which states that taxpayers may rely on them until final Treasury regulations are issued, this withholding tax does not apply to payments of gross proceeds from a sale or other disposition of common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY CHANGES IN APPLICABLE LAW SUBSEQUENT TO THE DATE HEREOF.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees, donees, transferees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their securities covered hereby on the Nasdaq Capital Market, or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities 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;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale;
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities that require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders also may transfer the securities in other circumstances, in which case the transferees, pledgees, donees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales (it being understood that the selling stockholders shall not be deemed to be underwriters solely as a result of their participation in this offering). In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of the date that the securities (i) have been sold, pursuant to this prospectus or pursuant to Rule 144, or (ii) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, and without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from sales of any shares of common stock by the selling stockholders.

We cannot assure you that the selling stockholders will sell all or any portion of the shares of common stock offered hereby. We are registering the resale of shares of our common stock to provide the selling stockholders with freely tradable securities, but the registration of such shares does not necessarily mean that any of such shares will be offered or sold by the selling stockholders pursuant to this prospectus or at all.

To the extent required, this prospectus may be amended and/or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

The validity of the common stock being offered by this prospectus has been passed upon for us by Brownstein Hyatt Farber Schreck, LLP, Las Vegas, Nevada.

EXPERTS

The consolidated financial statements of Pieris Pharmaceuticals, Inc. as of December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Palvella Therapeutics, Inc. as of December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP , independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains our filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at www.sec.gov.

We also make available free of charge on or through our website at www.palvellatx.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnishes it to the SEC. The website addresses are inactive textual references and except as specifically incorporated by reference into this prospectus, information on those websites is not part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement or documents incorporated by reference in the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

If you would like to request documents, please send a request in writing or by telephone to the following address:

Palvella Therapeutics, Inc.
125 Strafford Ave
Suite 360
Wayne, PA 19087
(484) 253-1461

INDEX TO FINANCIAL STATEMENTS

Pieris Pharmaceuticals, Inc.

Palvella Therapeutics, Inc.

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 19,363	$ 17,396
Short term investments	—	8,970
Accounts receivable	373	572
Receivable from public grants	—	3,141
Other receivables	506	2,326
Assets held for sale, property and equipment	—	2,188
Prepaid expenses and other current assets	280	4,087
Total current assets	$ 20,522	$ 38,680
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 801	$ 3,372
Accrued expenses and other current liabilities	3,453	8,550
Total current liabilities	4,254	11,922
Stockholders' equity:		
Preferred stock	—	—
Common stock	1	1
Additional paid-in capital	342,916	341,693
Accumulated other comprehensive income (loss)	(316)	28
Accumulated deficit	(326,333)	(314,964)
Total stockholders' equity	16,268	26,758
Total liabilities and stockholders' equity	$ 20,522	$ 38,680

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

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue				
Customer revenue	$ —	$ 15,569	$ 6	$ 37,665
Collaboration revenue	—	3,951	47	3,846
Total revenue	—	19,520	53	41,511
Operating expenses				
Research and development	(446)	9,595	1,523	37,347
General and administrative	3,581	6,839	11,145	14,526
Asset impairment	—	14,893	—	14,893
Total operating expenses	3,135	31,327	12,668	66,766
Loss from operations	(3,135)	(11,807)	(12,615)	(25,255)
Other income				
Interest income	169	549	610	1,396
Grant income	—	—	—	3,612
Other income	79	506	636	288
Net loss	$ (2,887)	$ (10,752)	$ (11,369)	$ (19,959)
Other comprehensive income loss:				
Foreign currency translation	120	(204)	(343)	(159)
Unrealized gain (loss) on available-for-sale securities	—	2	(1)	74
Comprehensive loss	$ (2,767)	$ (10,954)	$ (11,713)	$ (20,044)
Net loss per share				
Basic	$ (2.19)	$ (8.70)	$ (8.84)	$ (18.33)
Diluted	$ (2.19)	$ (8.70)	$ (8.84)	$ (18.33)
Weighted average number of common shares outstanding				
Basic	1,320	1,236	1,285	1,089
Diluted	1,320	1,236	1,285	1,089

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

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(unaudited, in thousands)

For the Three Months Ended September 30, 2023 and 2024

	Preferred shares		Common shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total Stockholders' equity
	No. of shares	Share capital	No. of shares	Share capital				
Balance as of June 30, 2023	16	$ —	1,236	$ 1	$ 340,262	$ (137)	$ (299,628)	$ 40,498
Net loss	—	—	—	—	—	—	(10,752)	(10,752)
Stock based compensation expense	—	—	—	—	966	—	—	966
Foreign currency translation adjustment	—	—	—	—	—	(204)	—	(204)
Unrealized gain on investments	—	—	—	—	—	2	—	2
Balance at September 30, 2023	16	$ —	1,236	$ 1	$ 341,228	$ (339)	$ (310,380)	$ 30,510
Balance as of June 30, 2024	16	$ —	1,320	$ 1	$ 342,586	$ (436)	$ (323,446)	$ 18,705
Net loss	—	—	—	—	—	—	(2,887)	(2,887)
Stock based compensation expense	—	—	—	—	330	—	—	330
Foreign currency translation adjustment	—	—	—	—	—	120	—	120
Balance at September 30, 2024	16	$ —	1,320	$ 1	$ 342,916	$ (316)	$ (326,333)	$ 16,268

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(unaudited, in thousands)

For the Nine Months Ended September 30, 2023 and 2024

	Preferred shares		Common shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total Stockholders' equity
	No. of shares	Share capital	No. of shares	Share capital				
Balance at December 31, 2022	16	$ —	931	$ 1	$ 318,603	$ (254)	$ (290,421)	$ 27,929
Net loss	—	—	—	—	—	—	(19,959)	(19,959)
Stock based compensation expense	—	—	—	—	2,898	—	—	2,898
Foreign currency translation adjustment	—	—	—	—	—	(159)	—	(159)
Unrealized loss on investments	—	—	—	—	—	74	—	74
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	1	—	52	—	—	52
Issuance of common stock pursuant to ATM offering program, net of $0.7 million in offering costs	—	—	303	—	19,675	—	—	19,675
Balance at September 30, 2023	16	$ —	1,236	$ 1	$ 341,228	$ (339)	$ (310,380)	$ 30,510
Balance at December 31, 2023	16	$ —	1,237	$ 1	$ 341,693	$ 28	$ (314,964)	$ 26,758
Net loss	—	—	—	—	—	—	(11,369)	(11,369)
Stock based compensation expense	—	—	—	—	1,223	—	—	1,223
Foreign currency translation adjustment	—	—	—	—	—	(343)	—	(343)
Unrealized gain on investments	—	—	—	—	—	(1)	—	(1)
Round-Up shares from the 1-for-80 reverse split effective April 23, 2024	—	—	83	—	—	—	—	—
Balance at September 30, 2024	16	$ —	1,320	$ 1	$ 342,916	$ (316)	$ (326,333)	$ 16,268

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (11,369)	$ (19,959)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization (accretion)	(30)	2,102
Right-of-use asset accretion	—	(98)
Stock-based compensation	1,223	2,898
Gain on sale of fixed assets	(225)	
Asset impairment	—	14,893
Prepaid rent	1,118	—
Realized investment losses	—	(53)
Other non-cash transactions	864	(129)
Changes in operating assets and liabilities	89	(33,804)
Net cash used in operating activities	(8,330)	(34,150)
Investing activities:		
Purchases of property and equipment	—	(184)
Proceeds from maturity of investments	9,000	24,007
Proceeds on sale of fixed assets	2,318	—
Purchases of investments	—	(15,270)
Net cash provided by investing activities	11,318	8,553
Financing activities:		
Proceeds from employee stock purchase plan	—	52
Proceeds from issuance of common stock resulting from ATM sales, net of $0.7 million in transaction costs	—	19,729
Net cash provided by financing activities	—	19,781
Effect of exchange rate change on cash and cash equivalents	(1,021)	75
Net increase in cash and cash equivalents	1,967	(5,741)
Cash and cash equivalents at beginning of period	17,396	38,635
Cash and cash equivalents at end of period	$ 19,363	$ 32,894
Supplemental cash flow disclosures:		
Net unrealized gain (loss) on investments	$ (1)	$ 74

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

PIERIS PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Corporate Information

Pieris Pharmaceuticals, Inc., or the Company or Pieris, was founded in May 2013, and acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company which was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries, hereinafter collectively Pieris, or the Company, is a biopharmaceutical company that, prior to July of 2023, discovered and developed Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Pieris' clinical pipeline consists of immuno-oncology, or IO, programs partnered with several major multi-national pharmaceutical companies. Pieris' corporate headquarters is located in Boston, Massachusetts. Pieris also maintains office space in Ismaning, Germany. The Company's core Anticalin technology and platform was developed in Germany.

On July 18, 2023, the Company announced its intention to explore engaging in one or more strategic transactions, including mergers, reverse mergers, acquisitions, other business combinations or sales of assets, or other strategic transactions. This decision was related to events that impacted the Company's inhaled respiratory franchise in connection with AstraZeneca's discontinuation of enrollment of the Phase 2a study for elarekibep, an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma. As part of this initiative, the Company engaged Stifel, Nicolaus & Company, Incorporated to serve as its advisor in its review of strategic transactions.

Also on July 18, 2023, the Company's Board of Directors approved a reduction in the Company's workforce by approximately 70%. Since July of 2023, and continuing through September 30, 2024, the Company took additional steps to reduce its operating footprint including terminating its remaining lease obligations in Germany and winding down its proprietary inhaled respiratory programs. The Company also has opted out and terminated programs where possible to reduce operating costs. Further reductions in the workforce have occurred based upon these actions. As a result, the Company has incurred approximately $7.5 million of severance costs and other related termination benefits in 2023 as the service period to earn such benefits is considered complete.

Approximately $2.4 million of the termination benefits were paid in 2023. The Company expects approximately $4.3 million of the termination benefits to be paid through the end of 2024, with the remainder of termination benefits to be paid in 2025.

On March 27, 2024, the Company announced the implementation of a new strategy along with relevant cost-saving measures that are expected to extend its cash runway into at least 2027, while maximizing its ability to capture the potential milestones from its partnered 4-1BB bispecific Mabcalin® protein IO assets. The Company may be entitled to aggregate milestones of up to approximately $15.0 million upon first patient dosed in the Phase 2 trials for SGN-BB228 and BOS-342, which are currently in Phase 1 clinical development, and up to approximately $40.0 million upon first patient dosed in pivotal clinical trials for SGN-BB228 and BOS-342.

On July 23, 2024, the Company and its wholly-owned subsidiary, Polo Merger Sub, Inc., or Merger Sub, entered into an Agreement and Plan of Merger (the "Merger Agreement") with Palvella Therapeutics, Inc., or Palvella, discussed further in Note 11, whereby Merger Sub will merge with and into Palvella, with Palvella continuing as a wholly-owned subsidiary of the Company and the surviving corporation of the merger, or the Merger. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, (i) each then-outstanding share of Palvella capital stock will be converted into the right to receive a number of shares of the Company's common stock equal to the Exchange Ratio as defined in the Merger Agreement; and (ii) each then-outstanding Palvella stock option to purchase Palvella common stock will be assumed by the Company. Each of the Company and Palvella has agreed to customary representations, warranties and covenants in the Merger Agreement, including, among others, covenants relating to (1) using reasonable best efforts to obtain the requisite approvals of their respective stockholders, (2) non-solicitation of alternative acquisition proposals, (3) the conduct of their respective businesses during the period between the date of signing the Merger Agreement and the closing of the Merger, (4) the Company using its commercially reasonable efforts to maintain the existing listing of the Company's common stock on Nasdaq and the Company causing the shares of the Company's common stock to be issued in connection with the Merger to be approved for listing on Nasdaq prior to the closing of the Merger and (5) the Company filing with the U.S. Securities and Exchange Commission, or the SEC, and causing to become effective a registration statement to register the shares of the Company's common stock to be issued in connection with the Merger.

On August 7, 2024, the Company entered into a Subscription and Investment Representation Agreement with James Geraghty, Chairman of the Company's Board of Directors, or the Purchaser, pursuant to which the Company agreed to issue and sell one (1) share of the Company's Series F Preferred Stock, par value $0.001 per share, to the Purchaser for $1.00 cash. The sale closed on August 7, 2024. The Series F Preferred Stock have no voting rights other than the right to vote on a proposed amendment to the Company's amended and restated articles of incorporation to effect an increase in the number of authorized shares of the Company's common stock, or the Authorized Share Increase Proposal. Each share of Series F Preferred Stock outstanding on the record date entitles the holder thereof to 25,000,000 votes on theAuthorized Share Increase Proposal, and all shares of Series F Preferred Stock held by such holder must and will be voted, without further action by such holder, in the same proportion as the aggregate shares of Pieris common stock (excluding any shares of Pieris common stock that are not voted) that are voted on the Authorized Share Increase Proposal.

As of September 30, 2024, cash and cash equivalents were $19.4 million. For the three months ended September 30, 2024 and 2023, the Company had a net loss of $2.9 million and $10.8 million, respectively. For the nine months ended September 30, 2024 and 2023, the Company had net losses of $11.4 million and $20.0 million, respectively. The Company has incurred net losses since inception and had an accumulated deficit of $326.3 million as of September 30, 2024. Net losses and negative cash flows from operations have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital. The Company expects to continue to incur operating losses for the foreseeable future.

The Company has historically devoted substantially all of its financial resources and efforts to research and development and general and administrative expenses to support the discovery and development of Anticalin-based drugs. Going forward, as part of the Company's previous decision to implement measures to maximize its ability to capture potential milestones from its partnered programs with Pfizer and Boston Pharmaceuticals (all as defined in Note 3 below) and the Company's plan to consummate the potential Merger, subject to stockholder approval, the Company has discontinued all research and development efforts and continues to reduce discretionary expenditures and other fixed or variable personnel costs. The Company believes that its currently available funds will be sufficient to fund its operations through at least the next twelve months from the issuance of this Quarterly Report on Form 10-Q. The Company's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2—Summary of Significant Accounting Policies, in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023. There have been no material additions to the significant accounting policies for thenine months ended September 30, 2024.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2024 are not necessarily indicative of results that may be expected for the year ending December 31, 2024. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on March 29, 2024.

Basis of Presentation and Use of Estimates

The accompanying unaudited condensed consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries were prepared in accordance with U.S. GAAP. The unaudited condensed consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

Effective at 5:00 p.m. Eastern Time on April 22, 2024, the Company effected a 1-for-80 reverse stock split of its common stock, or the Reverse Split, with any fractional shares resulting from the Reverse Split rounded up to the next whole share of common stock. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in this Quarterly Report on Form 10-Q have been restated to reflect the Reverse Split on a retroactive basis.

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition; deferred tax assets, deferred tax liabilities and valuation allowances; beneficial conversion features; fair value of stock options, preferred stock, and warrants; fair value of assets held for sale; and prepaid and accrued clinical trial expenses. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management's estimates, judgments and assumptions.

Cash, Cash Equivalents and Investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of 90 days or less from the purchase date and for which there is an active market are considered to be cash equivalents. The Company's investments are comprised of money market, asset backed securities, government treasuries and corporate bonds that are classified as available-for-sale in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its balance sheets.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive loss on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of other income.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than temporary, the Company considers its intent to sell or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment and changes in value subsequent to period end.

Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements. Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents, investments, and accounts receivable. The Company's cash, cash equivalents, and investments are held in accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimize the exposure to concentration of credit risk. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable historically consisted of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

Fair Value Measurement

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency.
- Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (see Note 5).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value.

Property and Equipment

Property and equipment are recorded at acquisition cost, less accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the remaining estimated useful lives of the assets. Maintenance and repairs to these assets are charged to expenses as occurred. As of the period ended September 30, 2024, the Company did not have any property and equipment recorded on the condensed consolidated balance sheet.

If the criteria in *ASC Topic 360 Property, Plant and Equipment* are met, a long-lived asset is classified as held for sale. The long-lived asset is reported at the lower of its carrying value or fair value less cost to sell beginning in the period the held for sale criteria are met. The carrying amount of the asset will be adjusted each reporting period for subsequent changes in fair value less costs to sell. A loss is recognized for any subsequent write-down to fair value less cost to sell. A gain is recognized for any subsequent increase in fair value less cost to sell, but not in excess of the cumulative loss previously recognized. Once classified as held for sale, depreciation and amortization are no longer recorded for any long-lived assets included in the disposal group.

Impairment of Long-lived Assets

The Company reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which *may* include: (i) licenses, or options to obtain licenses, to Pieris' Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with a collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research and development activities, payments based upon the achievement of certain milestones, and royalties on product sales. There are *no* performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. As the Company's intellectual property assets are considered to be located in Germany, the Company records all consolidated revenue in its subsidiary, Pieris Pharmaceuticals GmbH.

Collaborative Arrangements

The Company considers the nature and contractual terms of an arrangement and assesses whether the arrangement involves a joint operating activity pursuant to which it is an active participant and exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and exposed to the significant risks and rewards with respect to the arrangement, it accounts for these arrangements pursuant to ASC Topic 808, *Collaborative Arrangements*, or ASC 808, and applies a systematic and rational approach to recognize revenue. The Company classifies payments received as revenue and payments made as a reduction of revenue in the period in which they are earned. Revenue recognized under a collaborative arrangement involving a participant that is not a customer is presented as Collaboration Revenue in the condensed consolidated statement of operations.

Revenue from Contracts with Customers

In accordance with ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied.

The Company evaluates all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

Licensing arrangements are analyzed to determine whether the promised goods or services, which often include licenses, research and development services and governance committee services, are distinct or whether they must be accounted for as part of a combined performance obligation. If the license is considered not to be distinct, the license would then be combined with other promised goods or services as a combined performance obligation. If the Company is involved in a governance committee, it assesses whether its involvement constitutes a separate performance obligation. When governance committee services are determined to be separate performance obligations, the Company determines the fair value to be allocated to this promised service.

Certain contracts contain optional and additional items, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. An option that is considered a material right is accounted for as a separate performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, the Company estimates the amount of variable consideration by using the most likely amount method. In making this assessment, the Company evaluates factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period the Company re-evaluates the probability of achievement of such variable consideration and any related constraints. The Company will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. For potential research and development service payments, the Company estimates the amount of variable consideration by using the expected value method, including any approved budget updates arising from additional research or development services.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless a portion of the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or, in the case of certain variable consideration, to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amount the Company would expect to receive for each performance obligation.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

Revenue recognized under an arrangement involving a participant that is a customer is presented as Customer Revenue.

Milestones and Royalties

The Company aggregates milestones into four categories: (i) research milestones, (ii) development milestones, (iii) commercial milestones, and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale, including regulatory approval. Sales milestones are certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount.

There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur. For revenues from research and development milestones, payments will be recognized consistent with the recognition pattern of the performance obligation to which they relate.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Commercial milestones and sales royalties are determined by sales or usage-based thresholds and will be accounted for under the royalty recognition constraint as constrained variable consideration.

The Company calculates the maximum amount of potential milestones achievable under each collaboration agreement and discloses such potential future milestones for all current collaborations using such a maximum calculation.

Contract Balances

The Company recognizes a contract asset when the Company transfers goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e., accounts receivable). A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. The contract liabilities (i.e., deferred revenue) primarily relate to contracts where the Company has received payment but has not yet satisfied the related performance obligations.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all Company obligations under the agreement have been fulfilled.

Costs to Obtain and Fulfill a Contract with a Customer

Certain costs to obtain customer contracts, including success-based fees paid to third-party service providers, and costs to fulfill customer contracts are capitalized in accordance with FASB ASC Topic 340, *Other Assets and Deferred Costs*, or ASC 340. These costs are amortized to expense on a systemic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates. The Company will expense the amortization of costs to obtain customer contracts to general and administrative expense and costs to fulfill customer contracts to research and development expense.

Government Grants

The Company recognizes grants from governmental agencies when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received. The Company evaluates the conditions of each grant as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant will be received as a result of meeting the necessary conditions. Grants are recognized in the condensed consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Grant income is included as a separate caption within Other income (expense) in the condensed consolidated statements of operations.

Leases

In accordance with accounting standards update, or ASU, No. 2016-2, Leases (Topic 842), or ASC 842, and for each of the Company's leases, the following is recognized: (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date.

The Company determines if an arrangement is a lease at inception. The Company's contracts are determined to contain a lease within the scope of ASC 842 when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term and based on observable market data points. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis.

The Company typically only includes an initial lease term in its assessment of a lease agreement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The expected lease term includes noncancellable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

When a lease is terminated in its entirety, the corresponding lease liability and right-of-use asset are adjusted to zero. Any difference between the carrying amounts of the right-of-use asset and lease liability as compared to the termination payment is recorded in the statement of operations as a gain or loss.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, that requires a public entity to disclose significant segment expenses and other segment items on an annual and interim basis and provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. It requires a public entity to also disclose the title and position of the Chief Operating Decision Maker. The ASU will be effective for all entities for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the effect on the condensed consolidated financial statements.

On December 14, 2023, the FASB issued ASU 2023-09, or ASU 2023-09, Improvements to Income Tax Disclosures. The standard requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. ASU 2023-09 applies to all entities subject to income taxes. For public business entities, the new requirements will be effective for annual periods beginning after December 15, 2024. For entities other than public business entities, the requirement will be effective for annual periods beginning after December 15, 2025. The Company is currently evaluating the effect on the condensed consolidated financial statements.

3. Revenue

General

The Company has not generated revenue from product sales. The Company has generated revenue from contracts with customers (option, license and collaboration agreements), which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

The Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Pfizer (formerly Seagen)	$ —	$ 9,179	$ 6	$ 14,088
AstraZeneca	—	3,909	—	8,399
Servier	—	3,951	47	3,846
Genentech	—	—	—	12,697
Boston Pharmaceuticals	—	2,481	—	2,481
Total Revenue	$ —	$ 19,520	$ 53	$ 41,511

As of September 30, 2024, under the Company's existing strategic partnerships and other license agreements, the Company could receive the following potential milestone payments (in millions):

	Research, Development, Regulatory & Commercial Milestones	Sales Milestones
Pfizer (formerly Seagen)	$ 759	$ 450
Boston Pharmaceuticals	85	265
Total potential milestone payments	$ 844	$ 715

Strategic Partnerships

Genentech

On May 19, 2021, the Company and Genentech, Inc., or Genentech, entered into a Research Collaboration and License Agreement, or the Genentech Agreement, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage the Company's proprietary Anticalin technology. Upon signing the Genentech Agreement, Genentech paid the Company a $20 million upfront fee.

Under the terms of the Genentech Agreement, the Company was responsible for discovery and preclinical development of two initial programs. In April and May 2023, Genentech and the Company decided to discontinue the discovery-stage programs in ophthalmology and respiratory, respectively, for scientific reasons. Pursuant to this decision, the material right performance obligations related to the target swaps for these programs also expired. Based on these decisions, there are no more active performance obligations remaining under the collaboration and the Company recognized all remaining revenue, or $12.5 million, under the collaboration in the three months ended June 30, 2023.

Genentech also had options to select two additional programs with the payment of a fee, which expired in May 2024. With the expiration of these options and no programs active or ongoing, the Genentech Agreement also expired.

Boston Pharmaceuticals

On April 24, 2021, the Company and BP Asset XII, Inc., or Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an Exclusive Product License Agreement, or the BP Agreement, to develop BOS-342, also referred to as PRS-342, a 4-1BB/GPC3 preclinical immuno-oncology Mabcalin® (antibody-Anticalin fusion) protein.

Under the terms of the BP Agreement, Boston Pharmaceuticals exclusively licensed worldwide rights to BOS-342. The Company received an upfront payment and is further entitled to receive development, regulatory and sales-based milestone payments, tiered royalties up to low double-digits on sales of BOS-342 and a percentage of consideration received by Boston Pharmaceuticals in the event of a sublicense of a program licensed under the BP Agreement or a change of control of Boston Pharmaceuticals.

The Company recognized the full transaction price as revenue in 2021 and has no remaining obligations. In August 2023, the first patient was dosed in the Boston Pharmaceuticals sponsored Phase 1/2 study of PRS-342/BOS-342 in hepatocellular carcinoma (HCC), for which the Company received a milestone payment of $2.5 million.

Pfizer (formerly Seagen)

On February 8, 2018, the Company entered into a license and collaboration agreement, or the Pfizer Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or the Pfizer Platform License, and together with the Pfizer Collaboration Agreement, the Pfizer Agreements, with Pfizer Inc., or Pfizer, pursuant to which the parties agreed to develop multiple targeted bispecific IO treatments for solid tumors and blood cancers.

Under the terms of the Pfizer Agreements, the companies agreed to pursue multiple antibody-Anticalin fusion proteins during the research phase. The Pfizer Agreements provide Pfizer an option to select up to three programs for further development, which Pfizer did, and Pfizer is responsible for developing, funding and commercializing each of these programs.

On March 24, 2021, the Company entered into a Second Pfizer Amendment (formerly the Second Seagen Amendment), to amend the existing immuno-oncology collaboration agreement relating to joint development and commercial rights for one program in the alliance. Under the Second Pfizer Amendment, the Company retains a co-promotion option in the United States for one program, while Pfizer remains solely responsible for the development and overall commercialization of that program. The Company will also be entitled to increased royalties from that program if it chooses to exercise the co-promotion option.

Under the Pfizer Agreements, the Company is eligible to receive other various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur, with the exception of the $5.0 million milestone as described in the following paragraph.

In January 2023, the Company achieved a milestone for the first program in the Pfizer collaboration for $5.0 million. The Company evaluated the recognition of the milestone under ASC 606 and concluded that the constraints on the milestone no longer existed as of December 31, 2022 and therefore recorded the full $5.0 million as revenue for the year ended December 31, 2022.

In September 2023, Pfizer and the Company entered into an amendment of the Second Pfizer Amendment that provides Pfizer with collaboration product licenses and no changes to the amounts achievable under the collaboration agreement. The effect of the September 2023 amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer. Subsequently, in December 2023, the transfer of the programs was fully approved by the combined joint steering committee. Accordingly, the Company recognized revenue of approximately $10.1 million for the delivery on its performance obligations related to the two programs for the year ended December 31, 2023. With this amendment, the Company has satisfied all remaining obligations under the collaboration.

AstraZeneca

On May 2, 2017, the Company entered into a license and collaboration agreement, or the AstraZeneca Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or AstraZeneca Platform License, and together with the AstraZeneca Collaboration Agreement, the AstraZeneca Agreements, with AstraZeneca AB, or AstraZeneca, which became effective on June 10, 2017, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

In addition to elarekibep (formerly known as PRS-060/AZD1402), or the AstraZeneca Lead Product, the Company and AstraZeneca agreed to collaborate, under the original terms of the AstraZeneca Collaboration Agreement, to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products. The first two discovery-stage programs were discontinued in 2022. The third discovery-stage program was discontinued in the second quarter of 2023, which led to recognition of $4.0 million of revenue in that same quarter.

In June 2023, based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by the Company, AstraZeneca notified us of its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep. There was no effect to revenue as a result of the discontinuation of this program.

On July 17, 2023, as a result of the non-clinical safety finding in the 13-week toxicology study of elarekibep in non-human primates, AstraZeneca notified the Company of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. As a result of this, the remaining amount of current deferred revenue, or $3.5 million, related to the fourth discovery-stage program was recognized in revenue in the third quarter of 2023. With the termination of the AstraZeneca Agreements, there are no more active programs or performance obligations related to the collaboration. Following the termination date, the Company determined that it would not continue development of the programs under the AstraZeneca Agreements.

Servier

In 2017, the Company entered into a license and collaboration agreement, or Servier Collaboration Agreement, and a non-exclusive Anticalin platform license agreement, or Servier Platform License Agreement, and together with the Servier Collaboration Agreement, the Servier Agreements, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, pursuant to which the Company and Servier agreed to initially pursue five bispecific therapeutic programs. The intention of the collaboration and defined programs was to combine antibodies from the Servier portfolio with one or more Anticalin proteins based on the Company's proprietary platform to generate innovative IO bispecific drug candidates.

Since inception, four of the five initially committed programs have been discontinued by Servier. The Company does not presently intend to continue development of the four discontinued programs but retains full rights to advance the development and commercialization of those products on a world-wide basis in the future.

In July 2023, the Company notified Servier of its decision to opt out of co-development and commercialization of S095012, also referred to as PRS-344, a 4-1BB/PD-L1 bispecific Mabcalin protein, in the United States. With the decision to opt out of co-development of S095012, the Company recognized the remaining revenue under the collaboration, or $4.7 million, in 2023 and there are no more active co-development programs under the collaboration.

On June 28, 2024, Servier provided the Company with a written notice of termination of the Servier Collaboration Agreement. Pursuant to the Servier Platform License Agreement, the Servier Platform License Agreement terminates upon termination of the Servier Collaboration Agreement. The Servier Collaboration Agreement and Servier Platform License Agreements will terminate effective December 27, 2024, or 180 days from the date on which Servier notified the Company of its intent to terminate both agreements.

With this notice, Servier will discontinue and cease dosing in the Phase 1 clinical study of S095012. Servier's decision to terminate both agreements was based on a potential safety concern in S095012 Phase 1 clinical studies. The Company does not intend to pursue any further development of S095012.

Contract Balances

The Company receives payments from its collaboration partners based on payments established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under each arrangement. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right is unconditional.

There were no additions to deferred revenue during thethree and nine months ended September 30, 2024. There were no reductions to deferred revenue for thethree and nine months ended September 30, 2024 and reductions to deferred revenue were$17.1 million and $38.7 million for the three and nine months ended September 30, 2023 respectively.

4. Grant Income

One of the Company's proprietary respiratory assets, PRS-220, an oral inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, was being developed as a local treatment for idiopathic pulmonary fibrosis, and other forms for fibrotic lung disorders. In June 2021, the Company received a €14.2 million (approximately $17.0 million) grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy (the Bavarian Grant) supporting research and development for post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis, or PASC-PF, also known as post-COVID-19 syndrome pulmonary fibrosis, or long COVID.

The Bavarian Grant provided partial reimbursement for qualifying research and development activities on PRS-220, including drug manufacturing costs, activities and costs to support an IND filing, and Phase 1 clinical trials costs. The Bavarian Grant provided reimbursement of qualifying costs incurred through December 2023, with submission for reimbursements allowed through February 2024, which was successfully completed by the Company. As of September 30, 2024, all reimbursable amounts subject to the Bavarian Grant have been received by the Company.

5. Cash, cash equivalents and investments

As of September 30, 2024 and December 31, 2023, cash, cash equivalents and investments comprised funds in depository, money market funds and U.S. treasury securities. The following tables present the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 at September 30, 2024 and December 31, 2023.

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2024				
Money market funds, included in cash equivalents	$ 11,893	$ 11,893	$ —	$ —
Total	$ 11,893	$ 11,893	$ —	$ —

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2023				
Money market funds, included in cash equivalents	$ 13,224	$ 13,224	$ —	$ —
Investments - US treasuries	8,970	8,970	—	—
Total	$ 22,194	$ 22,194	$ —	$ —

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of September 30, 2024.

The Company recorded no realized gains or losses from the maturity of available-for-sale securities during thethree and nine months ended September 30, 2024and recorded no realized gains or losses and $0.1 million in realized losses from the maturity of available-for-sale securities during the three and nine months ended September 30, 2023, respectively.

6. Assets Held for Sale

As of September 30, 2024 and December 31, 2023, assets held for sale are summarized as follows (in thousands):

	September 30, 2024	December 31, 2023
Laboratory furniture and equipment	$ —	$ 1,967
Office furniture and equipment	—	221
Assets held for sale	$ —	$ 2,188

At the end of the third quarter of 2023, as part of the Company's strategic process for maximizing the value of assets, the Company committed to a plan to prepare and sell all property and equipment held at the Hallbergmoos, Germany location. The sale of the assets was deemed probable as a result of management's decision, including the estimated timing of sale which was determined to be within a year of the decision. As a result of this decision, the property and equipment met the criteria for held-for-sale accounting.

The net book value of its long-lived assets, as of December 31, 2023 represents the Company's best estimate of the fair value less costs to sell that could be recovered related to lab and office equipment and furniture as part of the Company's initiative to monetize all remaining assets. As the estimated selling price less costs to sell are based primarily on unobservable inputs as they relate to the location and condition of the specific lab equipment and furniture, they are classified in Level 3 in the fair value hierarchy. In the nine months ended September 30, 2024, the Company conducted an auction, with the assistance of a third party, of its assets held for sale. After the conclusion of the auction, the Company recovered the total net book value of the assets held for sale and recorded a gain on the sale of the assets of $0.2 million within "Other income (loss)" in the accompanying condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2024.

7. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Compensation expense	$ 2,306	$ 6,448
Research and development fees	—	968
Accrued accounts payable	60	558
Other current liabilities	1,031	363
Accrued license obligations	56	213
Total	$ 3,453	$ 8,550

The compensation expense line item in the above table includes both severance and benefit costs associated with the Company's corporate restructuring actions announced in 2023, inclusive of those employees retained as the service period to earn such benefits is considered complete. The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs. Severance pay and related costs for certain retained employees are estimated to be paid through the end of 2024. The Company recorded these restructuring charges based on each employee's role to the respective research and development and general and administrative operating expense categories on its condensed consolidated statements of operations and comprehensive loss.

The following tables includes a roll forward of the restructuring activity and payments recorded for the three and nine months ended September 30, 2024 (in thousands):

	Severance and Benefits Costs
Balance at June 30, 2024	$ 2,850
Adjustments to restructuring charges	$ 183
Cash payments	(805)
Balance at September 30, 2024	$ 2,228

	Severance and Benefits Costs
Balance at December 31, 2023	$ 5,105
Adjustments to restructuring charges	$ (86)
Cash payments	(2,791)
Balance at September 30, 2024	$ 2,228

8. Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, stock options and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented.

A reconciliation of basic and diluted net loss per share is as follows (in thousands, except for per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (2,887)	$ (10,752)	$ (11,369)	$ (19,959)
Basic weighted average common shares outstanding	1,320	1,236	1,285	1,089
Diluted weighted average common shares outstanding	1,320	1,236	1,285	1,089
Basic net loss per share	$ (2.19)	$ (8.70)	$ (8.84)	$ (18.33)
Diluted net loss per share	$ (2.19)	$ (8.70)	$ (8.84)	$ (18.33)

As of September 30, 2024 and 2023, and as calculated using the treasury stock method, approximately 0.5 million of weighted average shares, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.
This amount includes approximately 0.1 million of warrants to purchase one share of the Company's common stock with an exercise price of $568.00. These were issued with a five-year term in connection with the 2019 private placement financing and expired in November of 2024.

9. Stockholders' Equity

Effective at 5:00 p.m. Eastern Time on April 22, 2024, the Company effected a 1-for-80 Reverse Split of its common stock. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in this Quarterly Report on Form 10-Q have been restated to reflect the Reverse Split on a retroactive basis.

The Company had 3,750,000 shares authorized and 1,320,240 shares and 1,236,688 shares of common stock issued and outstanding as of September 30, 2024 and December 31, 2023, respectively, with a par value of $0.001 per share.

The Company had 10,000,000 shares authorized, 15,618 shares of preferred stock issued and outstanding as of September 30, 2024 and 15,617 shares of preferred stock issued and outstanding as of December 31, 2023. Preferred stock has a par value of $0.001 per share, and the Series A-E convertible preferred stock converts on a factor of 13.34 common shares for each preferred share, and consists of the following:

- Series A Convertible, 85 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.
- Series B Convertible, 4,026 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.
- Series C Convertible, 3,506 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.
- Series D Convertible, 3,000 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.
- Series E Convertible, 5,000 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.
- Series F Preferred, 1 share issued and outstanding at September 30, 2024, and no shares issued and outstanding at December 31, 2023

Subscription and Investment Representation Agreement (Series F Preferred Stock)

On August 7, 2024, the Company entered into a Subscription and Investment Representation Agreement with the Purchaser, pursuant to which the Company agreed to issue and sell one (1) share of the Company's Series F Preferred Stock, par value $0.001 per share, to the Purchaser for $1.00 cash. The sale closed on August 7, 2024.

Voting Rights

The Series F Preferred Stock have no voting rights other than the right to vote on the Authorized Share Increase Proposal. Each share of Series F Preferred Stock

outstanding on the record date entitles the holder thereof to 25,000,000 votes on Authorized Share Increase Proposal, and all shares of Series F Preferred Stock held by such holder must and will be voted, without further action by such holder, in the same proportion as the aggregate shares of Pieris common stock (excluding any shares of Pieris common stock that are not voted) that are voted on the Authorized Share Increase Proposal. As an example, if 70% of the aggregate votes cast by Pieris common stock voting on the Authorized Share Increase Proposal are voted in favor thereof and 30% of the aggregate votes cast by Pieris common stock voting on the Authorized Share Increase Proposal are voted against such Proposal, then 70% of the votes entitled to be cast by the Series F Preferred Stock will be cast in favor of the Proposal and 30% of such votes will be cast against the Proposal. For purposes of the foregoing, abstentions and broker non-votes will not be considered votes cast.

Conversion and Redemption

Shares of the Series F Preferred Stock are not convertible into any other security, and are redeemable by the Company upon the earlier to occur of: (i) the order of the Pieris board of directors in its sole discretion, automatically and effective at such date and time as is determined and specified by the Pieris board of directors in its sole discretion and (ii) automatically and effective immediately after the effectiveness of the increase in the number of authorized shares of Pieris common stock proposed in the Authorized Share Increase Proposal. Upon redemption, the holder of the Series F Preferred Stock will receive cash consideration of $0.01 per share. Shares of the Series F Preferred Stock may not be transferred prior to their redemption without the prior written consent of the Pieris board of directors.

Other Rights and Restrictions

Each holder of Series F Preferred Stock has entered into a written agreement with the Company to attend the Pieris special meeting, to vote all shares of Series F Preferred Stock with regard to the Authorized Share Increase Proposal in the same proportion as the aggregate shares of Pieris common stock (excluding any shares of Pieris common stock that are not voted) are voted on the Authorized Share Increase Proposal and, upon request by the Company, to grant a designee of the Company an irrevocable proxy to vote the shares of Series F Preferred Stock in accordance with the foregoing.

2020 Employee, Director and Consultant Equity Incentive Plan

At the 2020 Annual Meeting of Stockholders, the Company's stockholders approved the 2020 Employee, Director and Consultant Equity Incentive Plan, or the 2020 Plan. The 2020 Plan permits the Company to issue up to 43,750 shares of common stock pursuant to awards granted under the 2020 Plan. Upon approval of the 2020 Plan, the 2019 Employee, Director and Consultant Equity Incentive Plan, or the 2019 Plan, was terminated; all unissued options were canceled and no additional awards will be made thereunder. All outstanding awards under the 2019 Plan will remain in effect and any awards forfeited from the outstanding awards will be allocated back into the 2020 Plan. There were approximately 19,746 shares remaining and available for grant under the 2019 Plan that terminated upon original approval of the 2020 Plan.

At the 2021 Annual Meeting of Stockholders, held on June 25, 2021, the Company’s stockholders approved the first amendment to the 2020 Plan to add 28,125 shares for issuance under the 2020 Plan. At the 2022 Annual Meeting of Stockholders held on June 22, 2022, the Company’s stockholders approved a second amendment to the 2020 Plan to add 37,500 shares of common stock for issuance under the 2020 Plan. At the 2023 Annual Meeting of Stockholders held on June 21, 2023, the Company’s stockholders approved a third amendment to the 2020 Plan to add 75,000 shares of common stock for issuance under the 2020 Plan. As of September 30, 2024, there are 333,145 shares remaining and available for grant under the 2020 Plan.

2023 Employee Stock Purchase Plan

At the 2023 Annual Meeting of Stockholders, the Company’s stockholders approved the 2023 Employee Stock Purchase Plan, or the 2023 ESPP. The 2023 ESPP provides eligible employees with the opportunity to purchase shares of the Company's common stock at a discount, on a tax-favored basis, through regular payroll deductions in compliance with federal tax regulations. The Company has reserved 9,375 shares of common stock for issuance under the 2023 ESPP.

Open Market Sales Agreements

In August 2021, the Company established an at-the-market program, or ATM Program, under a sales agreement with Jefferies LLC, pursuant to which the Company may offer and sell shares of its common stock from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million. The ATM Program is offered under a shelf registration statement on Form S-3 that was filed with and declared effective by the SEC in August 2021. In November 2022, the sales agreement was amended to provide for an increase in the aggregate offering amount, such that under the ATM Program, as amended, the Company may offer and sell shares of its common stock, from time to time, up to an aggregate amount of gross sales proceeds of $75.0 million.

For the nine months ended September 30, 2024, the Company did not sell any shares under the ATM Program. For the nine months ended September 30, 2023, the Company sold 24.3 million shares for gross proceeds of $20.3 million under the ATM Program at an average stock price of $0.84 per share.

The Company is currently subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company's common stock held by non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of its common stock using its Form S-3, including under the ATM Program, until such time as its public float exceeds $75 million.

10. Leases

The Company generally conducts its operational functions in the United States remotely.

In October 2018, Pieris Pharmaceuticals GmbH entered into a lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. The Hallbergmoos Lease was subsequently amended in May 2019 and February 2020. The Hallbergmoos Lease, as amended, provided an initial rental term of 12.5 years, and a rental area of approximately 105,000 square feet.

In December 2023, Pieris Pharmaceuticals GmbH entered into an agreement to terminate the Hallbergmoos Lease, or the Lease Termination Agreement. Under the terms of the Lease Termination Agreement, Pieris Pharmaceuticals GmbH terminated the Hallbergmoos Lease in exchange for a termination fee of approximately €9.7 million, and vacated the majority of the premises by December 31, 2023, while continuing to occupy, through June 2024, a limited portion of the office space and using another portion of the former lab space to house its assets being held for sale.

There was no cash paid for amounts included in the measurement of the lease liabilities for the three and nine months ended September 30, 2024. Cash paid for amounts included in the measurement of the lease liabilities was $0.5 million and $1.6 million for the three and nine months ended September 30, 2023, respectively.

The following table summarizes operating lease costs included in operating expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease costs	$ —	$ 280	$ —	$ 862
Variable lease costs (1)	—	98	—	476
Total lease cost	$ —	$ 378	$ —	$ 1,338

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes, utilities, and other costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage.

11. Merger Agreement with Palvella Therapeutics, Inc.

On July 23, 2024, the Company and its wholly-owned subsidiary, Merger Sub entered into the Merger Agreement with Palvella whereby Merger Sub will merge with and into Palvella, with Palvella continuing as a wholly-owned subsidiary of the Company and the surviving corporation of the Merger. If the Merger is completed, the business of Palvella will continue as the business of the combined organization. Consummation of the Merger is contingent on certain closing conditions as identified in the Merger Agreement, including among others, (1) approval by the Company's stockholders of the Required Voting Proposals, as defined in the Merger Agreement, (2) approval by the Palvella stockholders of the adoption of the Merger Agreement, (3) Nasdaq's approval of the listing of the shares of the Company's common stock to be issued in connection with the Merger, (4) the effectiveness of the Registration Statement, and (5) consummation of the PIPE Financing, all in accordance with the terms of the Purchase Agreement.

Each party's obligation to consummate the Merger is also subject to other specified customary conditions, including the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the closing date of the Merger, generally subject to an overall material adverse effect qualification, the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger and the absence of any material adverse effect affecting the other party that is continuing on the closing date.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, as defined in the Merger Agreement, (i) each then-outstanding share of Palvella capital stock will be converted into the right to receive a number of shares of the Company's common stock equal to the Exchange Ratio as defined in the Merger Agreement; and (ii) each then-outstanding Palvella stock option to purchase Palvella common stock will be assumed by the Company, subject to adjustment as set forth in the Merger Agreement. In connection with the Merger, and contingent on the approval of the Company's stockholders, the Company intends to amend the amended and restated articles of incorporation of the Company to increase the number of shares of authorized common stock, change the corporate name of the Company to "Palvella Therapeutics, Inc." and adopt a new 2024 equity incentive plan. The provisions for calculating the Exchange Ratio are set forth in the Merger Agreement, and assume a valuation for Palvella equal to $95 million, and a valuation for Pieris equal to $21 million, provided, that (a) if Pieris' net cash as of the closing is greater than $11 million, then Pieris' valuation will be adjusted upwards on a dollar-for-dollar basis by the difference of: (i) Pieris' net cash, minus (ii) $11 million, and (b) if Pieris' net cash is less than $11 million, then Pieris' valuation will be adjusted downwards on a dollar-for-dollar basis by the difference of: (i) $11 million, minus (ii) Pieris' net cash.

For the purposes of calculating the Exchange Ratio for each of Pieris and Palvella, the total number of shares of capital stock of such company issued and outstanding immediately prior to the Merger, expressed on a fully-diluted and as-converted to common stock basis, calculated using the treasury stock method, will be included in the calculation of the Exchange Ratio. Shares of Pieris common stock underlying Pieris stock options outstanding immediately prior to the Effective Time with an exercise price per share of less than the volume weighted average closing trading price of a share of Pieris common stock on the Nasdaq for the five consecutive trading days ending five trading days immediately prior to the date upon which the Merger occurs will be deemed to be outstanding, calculated using the treasury stock method, and all shares of Palvella common stock underlying outstanding Palvella stock options, warrants and other derivative securities will be deemed to be outstanding, calculated using the treasury stock method, subject to certain exceptions set forth in the Merger Agreement.

Under the terms of the Merger Agreement, on a pro forma basis, it is expected that upon the closing of the Merger, pre-Merger Company stockholders will own approximately 18% of the combined company and pre-Merger Palvella stockholders will own approximately 82% of the combined company, based on the number of shares of the Company's common stock expected to be issued in connection with the Merger, in each case, prior to the issuance of shares under a proposed concurrent private financing. The percentage of the combined company that pre-merger Palvella stockholders and pre-merger Pieris stockholders will own upon the closing of the merger is subject to further adjustment based on the amount of Pieris' net cash at the time of closing.

In connection with the Merger, Pieris will seek the approval or ratification, as applicable, by its stockholders of, among other things, (a) the issuance of the shares of Pieris common stock issuable in connection with the Merger under the rules of The Nasdaq Stock Market LLC pursuant to the terms of the Merger Agreement, (b) amendments to the amended and restated articles of incorporation of Pieris to (i) increase the number of shares of authorized common stock and (ii) change the name of Pieris to "Palvella Therapeutics, Inc." (the approvals described in clause (a) and (b), the "Required Pieris Voting Proposals") and (c) the adoption of a new 2024 equity incentive plan, in each case, as described in the Merger Agreement.

Each of Pieris and Palvella has agreed to customary representations, warranties and covenants in the Merger Agreement, including, among others, covenants relating to (1) using reasonable best efforts to obtain the requisite approvals of their respective stockholders, (2) non-solicitation of alternative acquisition proposals, (3) the conduct of their respective businesses during the period between the date of signing the Merger Agreement and the closing of the Merger, (4) Pieris using its commercially reasonable efforts to maintain the existing listing of the Pieris common stock on Nasdaq and Pieris causing the shares of Pieris common stock to be issued in connection with the Merger to be approved for listing on Nasdaq prior to the closing of the Merger and (5) Pieris filing with the SEC and causing to become effective a registration statement to register the shares of Pieris common stock to be issued in connection with the Merger, or Registration Statement. The Registration Statement related to the Merger was included on the Form S-4 filed by the Company with the SEC on August 9, 2024, and was subsequently amended on September 23, 2024, October 15, 2024, November 5, 2024, and November 7, 2024. The Registration Statement was declared effective by the SEC on November 8, 2024.

The transaction is expected to close in the fourth quarter of 2024 and remains subject to stockholder approval.

Contingent Value Rights

At or prior to the Effective Time, Pieris will enter into a Contingent Value Rights Agreement, or CVR Agreement, with a rights agent, or Rights Agent, pursuant to which Pieris' pre-Merger capital stockholders will receive one contingent value right, or a CVR, for each outstanding share of Pieris common stock held by such stockholder, or share of common stock underlying preferred stock held by such stockholder, on such date. Each CVR will represent the contractual right to receive payments upon the receipt of payments by Pieris or any of its affiliates under certain strategic partner agreements, including existing collaboration agreements pursuant to which Pieris may be entitled to milestones and royalties in the future and other out-licensing agreements for certain of Pieris' legacy assets, and upon the receipt of certain research and development tax credits in favor of Pieris or any of its affiliates, in each case as set forth in, and subject to and in accordance with the terms and conditions of, the CVR Agreement.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that holders of CVRs will receive any amounts with respect thereto. The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the SEC. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in Pieris or any of its affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Termination Fees

The Merger Agreement contains certain termination rights of each of Pieris and Palvella, including, subject to compliance with the applicable terms of the Merger Agreement, the right of each party to terminate the Merger Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Merger Agreement under specified circumstances, Pieris may be required to pay Palvella a termination fee of $1.0 million and Palvella may be required to pay Pieris a termination fee of $2.0 million.

Securities Purchase Agreement

On July 23, 2024, and in connection with the executed Merger Agreement, Pieris entered into a securities purchase agreement, or the Purchase Agreement, with certain investors, including BVF Partners, L.P., an existing stockholder of Pieris, or the PIPE Investors, pursuant to which, among other things, the PIPE Investors have agreed to subscribe for and purchase (either for cash or in exchange for the termination and cancellation of outstanding convertible notes issued by Palvella), and Pieris agreed to issue and sell to the PIPE Investors, an aggregate of approximately 3,154,241 of shares of Pieris common stock at a price per share equal to $13.7299 multiplied by (x) 0.315478 *divided by* (y) the Exchange Ratio, or the Purchase Price, subject to adjustment as set forth in the Purchase Agreement, and/or in lieu of Pieris common stock to certain purchasers who so choose, pre-funded warrants, or the Pre-Funded Warrants, to purchase up to 2,592,585 shares of Pieris common stock at a purchase price per Pre-Funded Warrant equal to the Purchase Price minus $0.001, subject to adjustment as set forth in the Purchase Agreement, or the PIPE Financing. The Purchase Agreement contains customary representations and warranties of Pieris, on the one hand, and the PIPE Investors, on the other hand, and customary conditions to closing, including the consummation of the Merger. The gross proceeds from the PIPE Financing are expected to be approximately $78.9 million, before paying estimated expenses. The closing of the PIPE Financing is expected to occur in connection with and immediately following the consummation of the Merger.

The Pre-Funded Warrants do not expire, and each Pre-Funded Warrant will be exercisable at any time after the date of issuance of such Pre-Funded Warrant, subject to a beneficial ownership limitation. A holder of a Pre-Funded Warrant may not exercise such Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% or 9.99% of the number of shares of Pieris common stock outstanding immediately after giving effect to such exercise, provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%.

At or prior to the closing of the PIPE Financing, Pieris will enter into a registration rights agreement, or the Registration Rights Agreement, with the PIPE Investors pursuant to which the PIPE Investors will be entitled to certain resale registration rights with respect to shares of Pieris common stock issued to the PIPE Investors and any shares of Pieris common stock issued upon exercise of the Pre-Funded Warrants. Pursuant to the Registration Rights Agreement, the Company will be required to prepare and file a resale registration statement with the SEC within 30 days following the closing of the PIPE Financing. The Company shall use its commercially reasonable efforts to cause this registration statement to be declared effective by the SEC within 90 days following the closing of the PIPE Financing (or within 120 days following the PIPE Financing if the SEC reviews the registration statement).

PIERIS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Pieris Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pieris Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued and Prepaid Clinical Trial Expenses

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company records research and development expenses, which include expenses related to clinical trials, as incurred. The Company's determination of clinical trial costs incurred, as well as the related accrued and prepaid expenses at each reporting period incorporates judgment and utilizes various assumptions. Such judgments and assumptions include an evaluation of the information provided to the Company by third parties on actual costs incurred but not yet billed, estimated project timelines and patient enrollment. Payments for these activities are based on the terms of the individual arrangements, which differ from the pattern of costs incurred.

Auditing the Company's accrued and prepaid clinical trial expenses was especially challenging due to the large volume of information received from multiple sources that perform service on the Company's behalf. While the Company's estimates of accrued and prepaid clinical trial expenses are primarily based on information received related to each study from its vendors, the Company may need to make an estimate for additional costs incurred based on management judgment. Additionally, due to the duration of the work performed under clinical trials and the timing of invoices received from vendors, the actual amounts incurred are not typically known at the time the financial statements are issued.

How We Addressed the Matter in Our Audit

To evaluate the accrued and prepaid clinical trial expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the significant assumptions that are used by management to estimate the recorded accruals and prepayments. We corroborated the progress of research and development activities associated with clinical trials through discussion with the Company's research and development personnel that oversee the research and development activities. We inspected the Company's third-party contracts, amendments, and any pending change orders to assess the impact on amounts recorded. We also reviewed information received by the Company directly from vendors, which indicated the vendors' estimate of costs incurred to date. In addition, we performed analytics over fluctuations in accruals and prepaids by vendor throughout the period subject to audit and compared subsequent invoices received from third parties to amounts accrued.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2016.
Boston, Massachusetts
March 29, 2024, except Note 14, as to which the date is August 9, 2024

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 17,396	$ 38,635
Short term investments	8,970	20,534
Accounts receivable	572	5,810
Receivable from public grants	3,141	4,771
Other receivables	2,326	462
Assets held for sale, property and equipment	2,188	—
Prepaid expenses and other current assets	4,087	3,212
Total current assets	38,680	73,424
Property and equipment, net	—	16,992
Operating lease right-of-use assets, non-current	—	3,705
Other non-current assets	—	1,369
Total assets	$ 38,680	$ 95,490
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,372	$ 4,154
Operating lease liabilities, current	—	859
Accrued expenses and other current liabilities	8,550	10,746
Deferred revenues, current portion	—	20,824
Total current liabilities	11,922	36,583
Deferred revenue, net of current portion	—	18,734
Operating lease liabilities, non-current	—	12,244
Total liabilities	11,922	67,561
Commitments and Contingencies		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value per share, 10,000,000 shares authorized and 15,617 shares issued and outstanding at December 21, 2023 and 2022	—	—
Common stock, $0.001 par value per share, 3,750,000 shares authorized and 1,236,688 and 931,489 shares issued and outstanding at December 21, 2023 and 2022, respectively	1	1
Additional paid-in capital	341,693	318,603
Accumulated other comprehensive income	28	(254)
Accumulated deficit	(314,964)	(290,421)
Total stockholders' equity	26,758	27,929
Total liabilities and stockholders' equity	$ 38,680	$ 95,490

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Year Ended December 31,	
	2023	**2022**
Revenue		
Customer revenue	$ 38,711	$ 25,469
Collaboration revenue	4,099	433
Total revenue	42,810	25,902
Operating expenses		
Research and development	41,801	52,982
General and administrative	16,853	16,394
Asset impairment	13,912	—
Total operating expenses	72,566	69,376
Loss from operations	(29,756)	(43,474)
Other income (expense)		
Interest income	1,851	721
Grant income	3,612	8,173
Other (expense) income	(250)	1,303
Net loss	$ (24,543)	$ (33,277)
Other comprehensive (loss) income:		
Foreign currency translation	208	(1,010)
Unrealized gain (loss) on available-for-sale securities	74	(73)
Comprehensive loss	$ (24,261)	$ (34,360)
Net loss per share		
Basic and diluted	$ (21.80)	$ (35.90)
Weighted average number of common shares outstanding		
Basic and diluted	1,126	927

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands)

	Preferred shares		Common shares		Additional	Accumulated other		Total
	No. of shares	Share capital	No. of shares	Share capital	paid-in capital	comprehensive income (loss)	Accumulated deficit	Stockholders' equity
Balance as of January 1, 2022	16	$ —	903	$ 1	$ 307,069	$ 829	$ (257,144)	$ 50,755
Net loss	—	—	—	—	—	—	(33,277)	(33,277)
Foreign currency translation adjustment	—	—	—	—	—	(1,010)	—	(1,010)
Unrealized loss on investments	—	—	—	—	—	(73)	—	(73)
Stock based compensation expense	—	—	—	—	4,402	—	—	4,402
Issuance of common stock resulting from exercise of stock options	—	—	1	—	95	—	—	95
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	2	—	197	—	—	197
Issuance of common stock pursuant to ATM offering program, net of $0.3 million in offering costs	—	—	25	—	6,840	—	—	6,840
Balance at December 31, 2022	16	$ —	931	$ 1	$ 318,603	$ (254)	$ (290,421)	$ 27,929
Net loss	—	—	—	—	—	—	(24,543)	(24,543)
Foreign currency translation adjustment	—	—	—	—	—	208	—	208
Unrealized gain on investments	—	—	—	—	—	74	—	74
Stock based compensation expense	—	—	—	—	3,349	—	—	3,349
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	2	—	66	—	—	66
Issuance of common stock pursuant to ATM offering program, net of $0.7 million in offering costs	—	—	304	—	19,675	—	—	19,675
Balance at December 31, 2023	16	$ —	1,237	$ 1	$ 341,693	$ 28	$ (314,964)	$ 26,758

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2023	**2022**
Operating activities:		
Net loss	$ (24,543)	$ (33,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization (accretion)	1,904	2,770
Right-of-use asset (accretion) amortization	(123)	10
Stock-based compensation	3,349	4,402
Asset impairment	13,912	—
Realized investment gains	(53)	(376)
Other non-cash transactions	(124)	(91)
Changes in operating assets and liabilities:		
Accounts receivable	5,307	(2,624)
Prepaid expenses and other assets	1,018	(1,358)
Deferred revenue	(39,967)	(20,185)
Accounts payable	(789)	(4,208)
Accrued expenses and other current liabilities	(2,336)	(4,005)
Lease liability, prior to operating lease termination	(868)	(990)
Change in lease liability due to termination of operating lease	(10,506)	—
Net cash used in operating activities	(53,819)	(59,932)
Investing activities:		
Purchases of property and equipment	(171)	(1,041)
Proceeds from maturity of investments	35,008	28,200
Purchases of investments	(22,835)	(48,395)
Net cash provided by (used in) investing activities	12,002	(21,236)
Financing activities:		
Proceeds from exercise of stock options	—	95
Proceeds from employee stock purchase plan	66	197
Proceeds from issuance of common stock resulting from ATM sales, net of $0.7 million and $0.3 million in transaction costs, respectively	19,729	6,922
Net cash provided by financing activities	19,795	7,214
Effect of exchange rate change on cash and cash equivalents	783	(5,175)
Net decrease in cash and cash equivalents	(21,239)	(79,129)
Cash and cash equivalents at beginning of period	38,635	117,764
Cash and cash equivalents at end of period	$ 17,396	$ 38,635
Supplemental cash flow disclosures:		
Net unrealized gain (loss) on investments	$ 74	$ (73)
Property and equipment included in accounts payable	$ —	$ 193

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

PIERIS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Corporate Information

Pieris Pharmaceuticals, Inc., or the Company or Pieris, was founded in May 2013, and acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company which was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries, hereinafter collectively Pieris, or the Company, is a biopharmaceutical company that, prior to July of 2023, discovered and developed Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Pieris' clinical pipeline consists of immuno-oncology, or IO, programs partnered with several major multi-national pharmaceutical companies. Pieris' corporate headquarters is located in Boston, Massachusetts. Pieris also maintains office space in Hallbergmoos, Germany.

The Company's core Anticalin technology and platform was developed in Germany.

On July 18, 2023, the Company announced its intention to explore engaging in one or more strategic transactions, including mergers, reverse mergers, acquisitions, other business combinations or sales of assets, or other strategic transactions. This decision was related to events that impacted the Company's inhaled respiratory franchise, based upon AstraZeneca's discontinuation of enrollment of the Phase 2a study for elarekibep, an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma. As part of this initiative, the Company engaged Stifel, Nicolaus & Company, Incorporated to serve as its advisor in its review of strategic transactions.

Also on July 18, 2023, the Company's board of directors approved a reduction in the Company's workforce by approximately 70%. Since July of 2023, and through December 31, 2023, the Company took additional steps to reduce its operating footprint including terminating its remaining lease obligations in Germany and winding down its proprietary inhaled respiratory programs. The Company also has opted out and terminated programs where possible to reduce operating costs. Further reductions in the workforce have occurred based upon these actions. As a result, the Company has incurred approximately $7.5 million of severance costs and other related termination benefits in 2023 as the service period to earn such benefits is considered complete. The Company expects termination benefits to be paid through the end of 2024.

On March 27, 2024, the Company announced the implementation of a new strategy along with relevant cost-saving measures that are expected to extend its cash runway into at least 2027, while maximizing its ability to capture the potential milestones from its partnered 4-1BB bispecific Mabcalin protein IO assets. The Company may be entitled to aggregate milestones of up to $20 million upon first patient dosed in the phase 2 trials for SGN-BB228, S095012 (formerly PRS-344) and BOS-342, which are all currently in phase 1 clinical development, and up to $55 million upon first patient dosed in pivotal clinical trials for SGN-BB228, S095012 and BOS-342. To support this new strategy, the Company plans to discontinue all of its research and development efforts which it expects to complete by the middle of 2024, implement a workforce reduction that will impact additional employees and the executive leadership team which is expected to be implemented in the second quarter of 2024, and reduce the size of its Board of Directors, which is also expected to have implemented in the second quarter of 2024. In addition to the alliance management activities for its partnered programs, the Company remains committed to obtaining value for its products in prior development, including cinrebafusp alfa, as well as its proprietary platform capabilities by pursuing potential out-licensing or sales transactions. In addition to these potential transactions, the Company may also, from time-to-time, consider strategic opportunities that it believes may increase stockholder value.

As of December 31, 2023, cash, cash equivalents, and investments were $26.4 million. The Company's net loss was $24.5 million and $33.3 million for the years ended December 31, 2023 and 2022, respectively. The Company has incurred net losses since inception and had an accumulated deficit of $315.0 million as of December 31, 2023. Net losses and negative cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital. The Company expects to continue to incur operating losses for the foreseeable future.

The Company has historically devoted substantially all of its financial resources and efforts to research and development and general and administrative expenses to support the discovery and development of Anticalin-based drugs. Going forward, as part of the Company's decision to implement measures to maximize its ability to capture potential milestones from its partnered programs with Pfizer, Boston Pharmaceuticals, and Servier, the Company plans to discontinue all research and development efforts and reduce discretionary expenditures and other fixed or variable personnel costs. The Company believes that its currently available funds will be sufficient to fund its operations through at least the next twelve months from the issuance of this Annual Report on Form 10-K. The Company's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries were prepared in accordance with U.S. GAAP. The consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition; deferred tax assets, deferred tax liabilities and valuation allowances; fair value of held for sale assets; beneficial conversion features; fair value of stock options, preferred stock, and warrants; and prepaid and accrued clinical trial expenses. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management's estimates, judgments, and assumptions.

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries are translated from local currency into reporting currency, which is U.S. dollars, using the current exchange rate at the balance sheet date for assets and liabilities, and the weighted average exchange rate prevailing during the period for revenues and expenses. The functional currency for Pieris' foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive loss within stockholders' equity.

Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as other (expense) income, net in the consolidated statements of operations. Foreign currency gains and losses on available-for-sale investment transactions are recorded to other comprehensive income (loss) on the Company's balance sheet per Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 830, *Foreign Currency Matters.*

Cash, Cash Equivalents and Investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of 90 days or less from the purchase date and for which there is an active market are considered to be cash equivalents. The Company's investments are comprised of money market, asset backed securities, government treasuries, and corporate bonds that are classified as available-for-sale in accordance with FASB ASC 320, *Investments—Debt and Equity Securities.* The Company classifies investments available to fund current operations as current assets on its balance sheets.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive income (loss) on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of other income (expense).

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment, and changes in value subsequent to period end.

Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents, investments, and accounts receivable. The Company's cash, cash equivalents, and investments are held in accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable primarily consist of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

Fair Value Measurement

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, or ASC 820, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.
- Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments, if any (*Note 5*).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value.

Fair Values of Financial Instruments

The fair value of cash, accounts receivable, and accounts payable approximates the carrying value of these financial instruments because of the short-term nature of any maturities. The Company determines the estimated fair values of other financial instruments, using available market information and valuation methodologies, primarily input from independent third party pricing sources.

Accounts Receivable

Accounts receivable are recorded net of allowances for credit losses and represent amounts due from strategic partners. The Company monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for credit losses is necessary. The Company determined that no such reserve is needed as of December 31, 2023 and 2022. Historically, the Company has not had collectability issues.

Property and Equipment

Property and equipment are recorded at acquisition cost, less accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the remaining estimated useful lives of the assets. Maintenance and repairs to these assets are charged to expenses as occurred. Substantially all of the Company's fixed assets are located in Germany. The estimated useful life of the different groups of property and equipment is as follows:

Asset Classification	Estimated useful life (in years)
Leasehold improvements	shorter of useful life or remaining life of the lease
Laboratory furniture and equipment	8-14
Office furniture and equipment	5-13
Computer and equipment	3 - 7

If the criteria in *ASC 360 Property, Plant and Equipment* are met, a long-lived asset is classified as held for sale. The long-lived asset is reported at the lower of its carrying value or fair value less cost to sell beginning in the period the held for sale criteria are met. The carrying amount of the asset will be adjusted each reporting period for subsequent changes in fair value less cost to sell. A loss is recognized for any subsequent write-down to fair value less cost to sell. A gain is recognized for any subsequent increase in fair value less cost to sell, but not in excess of the cumulative loss previously recognized. Once classified as held for sale, depreciation and amortization are no longer recorded for any long-lived assets included in the disposal group.

Impairment of Long-lived Assets

The Company reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which *may* include: (i) licenses, or options to obtain licenses, to Pieris' Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with a collaborative partner. Payments to Pieris under these agreements *may* include upfront fees (which include license and option fees), payments for research and development activities, payments based upon the achievement of certain milestones, and royalties on product sales. There are *no* performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. As the Company's intellectual property assets are considered to be located in Germany, the Company records all consolidated revenue in its subsidiary, Pieris Pharmaceuticals, GmbH.

Collaborative Arrangements

The Company considers the nature and contractual terms of an arrangement and assesses whether the arrangement involves a joint operating activity pursuant to which it is an active participant and exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and exposed to the significant risks and rewards with respect to the arrangement, it accounts for these arrangements pursuant to ASC 808, *Collaborative Arrangements*, or ASC 808, and applies a systematic and rational approach to recognize revenue. The Company classifies payments received as revenue and payments made as a reduction of revenue in the period in which they are earned. Revenue recognized under a collaborative arrangement involving a participant that is not a customer is presented as Collaboration Revenue in the Statement of Operations.

Revenue from Contracts with Customers

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied.

The Company evaluates all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

Licensing arrangements are analyzed to determine whether the promised goods or services, which often include licenses, research and development services and governance committee services, are distinct or whether they must be accounted for as part of a combined performance obligation. If the license is considered not to be distinct, the license would then be combined with other promised goods or services as a combined performance obligation. If the Company is involved in a governance committee, it assesses whether its involvement constitutes a separate performance obligation. When governance committee services are determined to be separate performance obligations, the Company determines the fair value to be allocated to this promised service.

Certain contracts contain optional and additional items, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. An option that is considered a material right is accounted for as a separate performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, the Company estimates the amount of variable consideration by using the most likely amount method. In making this assessment, the Company evaluates factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period the Company re-evaluates the probability of achievement of such variable consideration and any related constraints. Pieris will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. For potential research and development service payments, the Company estimates the amount of variable consideration by using the expected value method, including any approved budget updates arising from additional research or development services.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless a portion of the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amount the Company would expect to receive for each performance obligation.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non- refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

Revenue recognized under an arrangement involving a participant that is a customer is presented as Customer Revenue.

Milestones and Royalties

The Company aggregates milestones into four categories: (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale, including regulatory approval. Sales milestones are certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount.

There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur. For revenues from research and development milestones, payments will be recognized consistent with the recognition pattern of the performance obligation to which they relate.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Commercial milestones and sales royalties are determined by sales or usage-based thresholds and will be accounted for under the royalty recognition constraint as constrained variable consideration.

The Company calculates the maximum amount of potential milestones achievable under each collaboration agreement and discloses such potential future milestones for all current collaborations using such a maximum calculation.

Contract Balances

The Company recognizes a contract asset when the Company transfers goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e., accounts receivable). A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. The contract liabilities (i.e., deferred revenue) primarily relate to contracts where the Company has received payment but has not yet satisfied the related performance obligations.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all Company obligations under the agreement have been fulfilled.

Costs to Obtain and Fulfill a Contract with a Customer

Certain costs to obtain customer contracts, including success-based fees paid to third-party service providers, and costs to fulfill customer contracts are capitalized in accordance with FASB ASC 340, *Other Assets and Deferred Costs*, or ASC 340. These costs are amortized to expense on a systemic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates. The Company will expense the amortization of costs to obtain customer contracts to general and administrative expense and costs to fulfill customer contracts to research and development expense.

Research and Development

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, pre-clinical and clinical costs, contract services, consulting, depreciation and amortization expense, and other related costs. Costs associated with acquired technology, in the form of upfront fees or milestone payments, are charged to research and development expense as incurred.

Income Taxes

The Company applies ASC Topic 740 *Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Where the Company determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The Company records interest and penalties related to uncertain tax positions as part of income tax expense.

The Tax Cuts and Jobs Act (TCJA) subjects a U.S. shareholder to tax on global-intangible low tax income (GILTI) earned by certain foreign subsidiaries. The Company has made an accounting policy election to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only.

Stock-based Compensation

The Company measures share-based payments in accordance with ASC Topic 718,*Stock Compensation.* Pieris records its stock-based compensation expense over the requisite service period and records forfeitures as they occur. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. For employee options, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite service period of the awards, less expense for actual forfeitures.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate and forfeitures of the underlying stock. Due to the limited operating history of the Company as a public entity and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid dividends, but may elect pay out dividends to stockholders in the future if we determine that there is sufficient cash and investments to achieve our near and long-term objectives.

All excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the Company's statement of operations and comprehensive loss. For the years ended December 31, 2023 and 2022, the Company did not record an income statement benefit for excess tax benefits as a valuation allowance is also required on these amounts.

Government Grants

The Company recognizes grants from governmental agencies when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received. The Company evaluates the conditions of each grant as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant will be received as a result of meeting the necessary conditions. Grants are recognized in the consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Grant income is included as a separate caption within Other income (expense), net in the consolidated statements of operations.

Leases

The Company accounts for leases pursuant to ASC 842 *Leases (Topic 842)*, or ASC 842. As a lessee, the Company is required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date.

The Company determines if an arrangement is a lease at inception. The Company's contracts are determined to contain a lease within the scope of ASC 842 when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset. In addition, the Company does not apply the recognition requirements in the lease standard to short-term leases (a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise) and does not separate lease and non-lease components for all asset classes. Any variable components of lease costs are excluded from lease payments and are recognized in the period incurred, including increases to rent based on German Consumer Price Index, or CPI.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term and based on observable market data points. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis.

The Company typically only includes an initial lease term in its assessment of a lease agreement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The expected lease term includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

When a lease is terminated in its entirety, the corresponding lease liability and right-of-use asset are adjusted to zero. Any difference between the carrying amounts of the right-of-use asset and lease liability as compared to the termination payment is recorded in the statement of operations as a gain or loss.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, the Company determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, the Company carries out an evaluation of disclosure requirements and considers possible accruals in the financial statements.

Segment Reporting

Operating segments are identified as components of an enterprise where separate discrete financial information is evaluated by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company's chief operating decision maker, or CODM, makes decisions based on the Company as a whole. The Company has determined that its CODM is its Chief Executive Officer.

Earnings per Share

Basic earnings per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents.

Diluted earnings per share attributable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share attributable to common stockholders' calculation, preferred stock, stock options, unvested restricted stock, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Recent Accounting Pronouncements Not Yet Adopted

The Company has considered recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the audited consolidated financial statements as a result of future adoption.

3. Revenue

General

The Company has not generated revenue from product sales. The Company has generated revenue from contracts with customers (option, license and collaboration agreements), which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

During the years ended December 31, 2023 and 2022, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Year Ended December 31,	
	2023	2022
AstraZeneca	$ 8,399	$ 9,117
Pfizer	15,134	8,287
Servier	4,099	5,359
Genentech	12,697	3,139
Boston Pharmaceuticals	2,481	—
Total Revenue	$ 42,810	$ 25,902

Under the Company´s existing strategic partnerships and other license agreements, the Company could receive the following potential milestone payments (in millions) as of December 31, 2023:

	Research, Development, Regulatory & Commercial Milestones	Sales Milestones
Pfizer	$ 759	$ 450
Servier	107	99
Boston Pharmaceuticals	85	265
Total potential milestone payments	$ 951	$ 814

Strategic Partnerships

Genentech

On May 19, 2021, the Company and Genentech, Inc., or Genentech, entered into a Research Collaboration and License Agreement, or the Genentech Agreement, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage the Company's proprietary Anticalin technology. Upon signing the Genentech Agreement, Genentech paid the Company a $20 million upfront fee. In addition, the Company may be eligible to receive additional milestone payments across multiple programs, as well as tiered royalty payments on net sales at percentages ranging from the mid-single to low double-digits, subject to certain standard reductions and offsets.

Under the terms of the Genentech Agreement, the Company was responsible for discovery and preclinical development of two initial programs. In April and May 2023, Genentech and the Company decided to discontinue the discovery-stage programs in ophthalmology and respiratory, respectively, for scientific reasons. Pursuant to this decision, the material right performance obligations related to the target swaps for these programs also expired. Based on these decisions, there aren't any active performance obligations remaining under the collaboration and the Company recognized all remaining revenue, or $12.5 million, under the collaboration in the second quarter of 2023.

The Genentech Agreement also provided an option to select additional programs, at Genentech's discretion, for a fee and this option expires in May 2024. If Genentech exercises its option to start additional programs, the Company would be eligible to receive additional milestone payments, as well as tiered royalty payments on net sales, subject to certain standard reductions and offsets. Genentech's options to nominate two additional collaboration targets of their choosing is subject to the legal availability of the target to be researched. As of December 31, 2023, any variable consideration related to the exercise of such options is considered fully constrained.

Boston Pharmaceuticals

On April 24, 2021, the Company and BP Asset XII, Inc., or Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an Exclusive Product License Agreement, or the BP Agreement, to develop PRS-342, a 4-1BB/GPC3 preclinical immuno-oncology Anticalin-antibody bispecific fusion protein.

Under the terms of the BP Agreement, Boston Pharmaceuticals exclusively licensed worldwide rights to PRS-342. The Company received an upfront payment of $10.0 million and is further entitled to receive development, regulatory and sales-based milestone payments, tiered royalties up to low double-digits on sales of PRS-342 and a percentage of consideration received by Boston Pharmaceuticals in the event of a sublicense of a program licensed under the BP Agreement or a change of control of Boston Pharmaceuticals. The Company also contributed $4.0 million toward manufacturing activities.

The Company completed all performance obligations in 2021, at which point the revenue was recorded from the upfront payment. In August 2023, the first patient was dosed in the Boston Pharmaceuticals sponsored Phase 1/2 study for BOS-342 in hepatocellular carcinoma, or HCC, for which the Company received a milestone payment.

Pfizer

On February 8, 2018, the Company entered into a license and collaboration agreement, or the Pfizer Collaboration Agreement (formerly the Seagen Collaboration Agreement), and a non-exclusive Anticalin platform technology license agreement, or the Pfizer Platform License (formerly the Seagen Platform License), and together with the Pfizer Collaboration Agreement, the Pfizer Agreements (formerly the Seagen Agreements), with Pfizer (formerly Seagen), pursuant to which they agreed to develop multiple targeted bispecific IO treatments for solid tumors and blood cancers.

Under the terms of the Pfizer Agreements, the companies pursued multiple Anticalin-antibody fusion proteins during the research phase. The Pfizer Agreements provide Pfizer a base option to select up to three programs for further development. Prior to the initiation of a pivotal trial, the Company may opt into global co-development and U.S. commercialization of the second program and share in global costs and profits on an equal basis. Pfizer will solely develop, fund and commercialize the other two programs. Pfizer may also decide to select additional candidates from the initial research phase for further development in return for the payment to us of additional fees, milestone payments, and royalties.

On March 24, 2021, the Company announced that Pfizer made a strategic equity investment in Pieris, and that the companies had entered into a Second Pfizer Amendment (formerly Second Seagen Amendment), in which their existing immuno-oncology collaboration agreement has been amended relating to joint development and commercial rights for one program in the alliance. Under the Second Pfizer Amendment, Pieris' option to co-develop and co-commercialize one of three programs in the collaboration was converted to a co-promotion option in the United States, with Pfizer solely responsible for the development and overall commercialization of that program. Pieris will also be entitled to increased royalties from that program in the event that it chooses to exercise the co-promotion option. In connection with the agreements described above, the Company and Pfizer entered into a subscription agreement, or the Pfizer Subscription Agreement (formerly the Seagen Subscription Agreement), pursuant to which the Company agreed to issue to Pfizer, and Pfizer agreed to acquire from the Company, 46,327 shares of the Company's common stock for a total purchase price of $13.0 million, or $280.80 per share, in a private placement transaction pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. The Pfizer Subscription Agreement includes a provision to the effect that Pfizer may ask the Company to file a registration statement to register the resale of the shares issued to Pfizer, at any time beginning on the date that is 60 calendar days from the date of issuance of the shares. The Company assessed the ASC 606 implications of the Pfizer Subscription Agreement and concluded that the fair value of the shares on a per share basis was $208.80 per share as of the transaction date. This resulted in a premium paid for the shares of $3.3 million, all of which was recorded in deferred revenue upon contract execution and allocated to the remaining performance obligations.

In the second quarter of 2022, the Company recorded approximately $1.5 million in revenue related to completion of the performance obligation for the expiration of the target swap under the second program in the collaboration.

Under the Pfizer Agreements, the Company is eligible to receive various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur, with the exception of the $5.0 million milestone as described in the following paragraph.

In January 2023, the Company achieved a milestone for the first program in the collaboration for $5.0 million. The Company evaluated the recognition of the milestone under ASC 606 and concluded that the constraints on the milestone no longer existed as of December 31, 2022 and therefore recorded the full $5.0 million as revenue for the year ended December 31, 2022.

In September 2023, Pfizer and the Company entered into an amendment of the Second Pfizer Amendment that provides Pfizer with collaboration product licenses and no changes to the amounts achievable under the collaboration agreement. The effect of the September 2023 amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer. Subsequently, in December 2023, the transfer of the programs was fully approved by the combined joint steering committee. Accordingly, the Company recognized revenue of approximately $10.1 million for the delivery on its performance obligations related to the two programs for the year ended December 31, 2023. With this amendment, the Company has satisfied all remaining obligations under the collaboration.

AstraZeneca

On May 2, 2017, the Company entered into a license and collaboration agreement, or the AstraZeneca Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or AstraZeneca Platform License, and together with the AstraZeneca Collaboration Agreement, the AstraZeneca Agreements with AstraZeneca AB, or AstraZeneca, which became effective on June 10, 2017, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under the AstraZeneca Agreements the parties agreed to advance several novel inhaled Anticalin proteins.

In addition to the Company's former lead inhaled drug candidate, PRS-060/AZD1402, or the AstraZeneca Lead Product, the Company and AstraZeneca, under the original terms of the AstraZeneca Collaboration Agreement, would also collaborate to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products. As of June 2023, the AstraZeneca Lead Product and three of the four AstraZeneca Collaboration Products had been discontinued. The first two discovery-stage programs were previously discontinued in 2022, which led to approximately $9.7 million in revenue recognized due to these discontinuations. Elarekibep and the third discovery-stage program were discontinued in the second quarter of 2023. The discontinuation of the third discovery program led to recognition of $4.0 million of revenue in the quarter ended June 30, 2023, while there was no revenue recognized as a result of the discontinuation of elarekibep.

The Company was responsible for advancing the AstraZeneca Lead Product through its phase 1 study, with the associated costs funded by AstraZeneca. The parties would collaborate thereafter to conduct a phase 2a study in asthma patients, with AstraZeneca continuing to fund development costs. After completion of a phase 2a study, Pieris had the option to co-develop the AstraZeneca Lead Product and also had a separate option to co-commercialize the AstraZeneca Lead Product in the United States. For the AstraZeneca Collaboration Products, the Company was responsible for the initial discovery of the novel Anticalin proteins, after which AstraZeneca would take the lead on continued development of the AstraZeneca Collaboration Products. The Company had the option to co-develop two of the four AstraZeneca Collaboration Products beginning at a pre-defined preclinical stage and would also have the option to co-commercialize these two programs in the United States, while AstraZeneca would be responsible for development and commercialization of the other programs worldwide.

On July 17, 2023, AstraZeneca notified the Company of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. AstraZeneca's decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by the Company. As a result of this, the remaining amount of current deferred revenue, or $3.5 million, related to the fourth discovery-stage program was recognized in revenue as of September 30, 2023. With the termination of the AstraZeneca Agreements, there are no more active programs or performance obligations related to the collaboration. Following the termination date, the Company determined that it would not continue development of the programs under the AstraZeneca Agreements.

The Company incurred $1.6 million of third-party success fees to obtain the contract with AstraZeneca. Upon adoption of ASC 606, the Company capitalized $1.1 million in accordance with ASC 340. In accordance with the termination of the AstraZeneca Agreements and recognition of remaining revenue, the Company also amortized the remaining deferred transactions costs to obtain the contract, or $0.3 million. Amortization for the year ended December 31, 2022 was $0.3 million.

Servier

In 2017, the Company entered into a license and collaboration agreement, or Servier Collaboration Agreement, and a non-exclusive Anticalin platform license agreement, or Servier Platform License, and together with the Servier Collaboration Agreement, the Servier Agreements with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, pursuant to which the Company and Servier agreed to initially pursue five bispecific therapeutic programs. The intention of the collaboration and defined programs was to combine antibodies from the Servier portfolio with one or more Anticalin proteins based on the Company's proprietary platform to generate innovative IO bispecific drug candidates, or the Collaboration products.

In the first quarter of 2022, the Company satisfied the performance obligation related to the material right for S095025 (PRS-352) which led to point-in-time recognition of revenue for $4.9 million of revenue previously deferred. In the fourth quarter of 2022, Servier discontinued development of S095025 based upon a strategic portfolio review. Since inception, four of the five initially committed programs have been discontinued by Servier. The Company does not presently intend to continue development of the four discontinued programs but retains full rights to advance the development and commercialization of those products on a world-wide basis in the future.

In July 2023, the Company notified Servier of its decision to opt out of co-development and commercialization of S095012 (PRS-344), a 4- 1BB/PD- L1 bispecific Mabcalin protein, in the U.S. Servier retains exclusive, even as to the Company, worldwide rights to the program, including the right to continue to advance development and potential commercialization of S095012 (PRS-344) in the U.S. As a result of the Company's decision to opt out of co-development, the Company will be entitled to increased royalty rates and potential royalties and milestones, if any, for S095012 (PRS-344) under the terms of the Servier Agreement. With the decision to opt out of co-development of S095012 (PRS-344), the Company recognized the remaining revenue under the collaboration, or $4.7 million, in 2023 and there are no more active co-development programs under the collaboration.

Contract Balances

The Company receives payments from its collaboration partners based on payments established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under each arrangement. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right is unconditional.

There were no additions to deferred revenue during the year ended December 31, 2023 and reductions to deferred revenue were $39.7 million for the year ended December 31, 2023.

4. Grant Income

One of the Company's proprietary respiratory assets is PRS-220, an oral inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, was being developed as a local treatment for idiopathic pulmonary fibrosis, and other forms for fibrotic lung disorders. In June 2021, the Company received a €14.2 million (approximately $17.0 million) grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy (the Bavarian Grant) supporting research and development for post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis, or PASC-PF, also known as post-COVID-19 syndrome pulmonary fibrosis, or "long COVID".

The Bavarian Grant provides partial reimbursement for qualifying research and development activities on PRS-220, including drug manufacturing costs, activities and costs to support an IND filing, and phase 1 clinical trials costs. The Bavarian Grant provides reimbursement of qualifying costs incurred through December 2023, with submission for reimbursements allowed through February 2024, which was successfully completed by the Company. The timing follows the expected development timeline of this program. Qualifying costs incurred may exceed the annual grant funding thresholds.

In addition, the Company is required to communicate if there is a change in control or other event that would impact the continuation of PRS-220 to the Bavarian project agency, in which case the Company may be required to refund some or all amounts received under the grant.

5. Cash, Cash Equivalents and Investments

As of December 31, 2023, cash, cash equivalents and investments comprised funds in depository, money market accounts and U.S. treasury securities. As of December 31, 2022, cash, cash equivalents and investments comprised funds in depository, money market accounts, U.S. and foreign treasury securities, asset-backed securities and corporate bonds. The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 at December 31, 2023.

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2023				
Money market funds, included in cash equivalents	$ 13,224	$ 13,224	$ —	$ —
Investments - US treasuries	8,970	8,970	—	—
Total	$ 22,194	$ 22,194	$ —	$ —

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2022				
Money market funds, included in cash equivalents	$ 17,618	$ 17,618	$ —	$ —
Investments - US treasuries	3,573	3,573	—	—
Investments - Foreign treasuries	896	896	—	—
Investments - Asset-backed securities	499	—	499	—
Investments - Corporate bonds	15,566	—	15,566	—
Total	$ 38,152	$ 22,087	$ 16,065	$ —

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of December 31, 2023.

Investments at December 31, 2023 consist of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments					
US treasuries	4-51	$ 8,969	$ 1	$ —	$ 8,970
Total		$ 8,969	$ 1	$ —	$ 8,970

The Company recorded realized losses from the maturity of available-for-sale securities of $0.1 million and realized gains of $0.4 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

6. Assets Held for Sale, Property and Equipment

As of December 31, 2023, assets held for sale are summarized as follows (in thousands):

	December 31, 2023
Laboratory furniture and equipment	$ 1,967
Office furniture and equipment	221
Assets held for sale	$ 2,188

At the end of the third quarter of 2023, as part of the Company's strategic process for maximizing the value of assets, the Company committed to a plan to prepare and sell all property and equipment held at the Hallbergmoos, Germany location. The sale of the assets was deemed probable as a result of management's decision, including the estimated timing of sale which was determined to be within a year of the decision. As a result of this decision, the property and equipment met the criteria for held-for-sale accounting.

The Company recorded impairment charges totaling $13.9 million, of which $1.8 million related to impairment of its right-of-use asset under the Hallbergmoos Lease (see Note 13) with the remaining related to a complete write-off of leasehold improvements and a partial impairment of the Company's other long-lived assets. The remaining $2.2 million in net book value of its long-lived assets represents the Company's best estimate of the fair value less costs to sell that could be recovered related to lab and office equipment and furniture as part of the Company's initiative to monetize all remaining assets. As the estimated selling price less costs to sell are based primarily on unobservable inputs as they relate to the location and condition of the specific lab equipment and furniture, they are classified in Level 3 in the fair value hierarchy. In the first quarter of 2024, the Company conducted an auction, with the assistance of a third party, of its assets held for sale. After the conclusion of the auction, the Company has recovered substantially all of the total net book value of the assets held for sale. The Company has further plans to sell all remaining assets in the second quarter of 2024.

As of December 31, 2022, property and equipment are summarized as follows (in thousands):

	December 31, 2022
Laboratory furniture and equipment	$ 11,970
Office furniture and equipment	1,861
Computer equipment	364
Leasehold improvements	12,444
Property and equipment, cost	26,639
Accumulated depreciation	(9,647)
Property and equipment, net	$ 16,992

Depreciation expense was $1.8 million and $2.3 million for the years ended December 31, 2023 and 2022, respectively. There were no other changes in accumulated depreciation other than the foreign currency impact.

7. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	Years Ended December 31,	
	2023	**2022**
Compensation expense	$ 6,448	$ 3,015
Research and development fees	968	5,758
Accrued accounts payable	558	1,245
Other current liabilities	363	483
Accrued license obligations	213	245
Total	$ 8,550	$ 10,746

The compensation expense line item in the above table includes both severance and benefit costs associated with the Company's corporate restructuring actions announced in 2023, inclusive of those employees retained as the service period to earn such benefits is considered complete. The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs. Severance pay and related costs for certain retained employees are estimated to be paid through the end of 2024. The Company recorded these restructuring charges based on each employee's role to the respective research and development and general and administrative operating expense categories on its consolidated statements of operations and comprehensive loss.

The following table includes a roll forward of the restructuring activity and payments recorded for the year ended December 31, 2023 (in thousands):

	Severance and Benefits Costs
Restructuring expenses	$ 7,523
Cash payments	$ (2,418)
Balance at December 31, 2023	$ 5,105

8. Income Taxes

The Company reported a loss before income taxes consisting of the following (in thousands):

	Years Ended December 31,	
	2023	**2022**
Domestic	$ (9,818)	$ (11,765)
Foreign	(14,726)	(21,512)
Loss before income taxes	$ (24,544)	$ (33,277)

The components of the provision for income taxes are as follows (in thousands):

	Years Ended December 31,	
	2023	**2022**
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision for income taxes	$ —	$ —

The reconciliation of the federal statutory rate to the Company's effective tax rate is as follows:

	2023	2022
Federal income tax rate	21.0%	21.0%
Foreign rate differential	0.7%	5.0%
State tax, net of federal benefit	3.8%	2.0%
Share-based awards compensation	(2.1)%	(2.2)%
Permanent items	(2.1)%	0.3%
Other	(1.0)%	1.0%
Release of uncertain tax position	22.7%	—%
Credits	0.8%	1.2%
Change in valuation allowance	(43.8)%	(28.3)%
Effective income tax rate	—%	—%

The components of deferred tax assets and liabilities related to net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income taxes purposes were as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 67,496	$ 54,845
Share-based awards compensation	2,624	3,112
Accrued expenses	461	216
R&D Credits	644	413
Depreciation and other	479	384
Unrealized foreign currency	(377)	359
Capitalized R&D	1,165	952
Lease liability	—	3,541
Total deferred tax assets	72,492	63,822
Deferred tax liabilities:		
Right-of-use asset	—	(3,270)
Accrued expenses	—	—
Total deferred tax liabilities	—	(3,270)
Less: valuation allowance:	(72,492)	(60,552)
Net deferred tax asset	$ —	$ —

The Company operates in multiple jurisdictions. Accordingly, the Company files U.S. federal and state income tax returns as well as returns in multiple foreign jurisdictions. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the United States or in its foreign jurisdictions to realize the full benefits of its deferred tax assets. As of December 31, 2023, the Company continues to maintain a full valuation allowance against all net deferred tax assets.

The cumulative amount of earnings of our foreign subsidiaries are expected to be permanently invested in the foreign subsidiaries. Deferred taxes have not been provided on the excess of book basis over tax basis, or the excess tax basis over book basis in the shares of our foreign subsidiaries because these basis differences are not expected to reverse in the foreseeable future and are essentially permanent in duration. Our intention is to reinvest the earnings of the foreign subsidiaries indefinitely.

The increase in the valuation allowance of deferred tax assets of $11.9 million for the year ended December 31, 2023 was primarily a result of the operating losses generated in current tax year.

As of December 31, 2023, the Company had net operating loss carryforwards for U.S. federal income tax purposes of $43.4 million and net operating loss carryforwards for state income tax purposes of $46.7 million. Federal tax loss carryforwards that were created prior to December 31, 2017 expire through 2037 and federal losses created after that date do not expire. State loss carryforwards expire starting in 2035. Pursuant to Section 382 of the Internal Revenue Code of 1986, or the Code, and similar state tax law, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss and tax credit carryforwards that may be used in future years. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation under Section 382 of the Code due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company completed a Section 382 study through December 31, 2020. Based on the study, the Company underwent an ownership change for Section 382 purposes which occurred in February 2018. As a result of the ownership change, the Company's net operating loss and tax credit carryforwards as of the ownership change dates are subject to limitation under Section 382; however, these limitations are not expected to result in any of the impacted net operating loss and tax credit carryforwards to expire unutilized. Any net operating losses or tax credits generated after the February 2018 change are not subject to this annual limitation. However, subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax. The Company is currently open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for the tax years ended 2019 through the current year. Carryforward tax attributes generated in years past may still be adjusted upon future examination if they have or will be used in a future period. The Company is not under examination by the Internal Revenue Service or any other jurisdictions for any tax years.

As of December 31, 2023, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately $187.6 million and $183.7 million respectively. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) of $1.2 million plus 60% of the exceeding taxable income and trade profit of such period and do not expire. In addition, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

As of December 31, 2023, the Company had gross U.S. federal and state research and development and other tax credit carryforwards of $0.5 million and $0.1 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2042 and 2037, respectively. As of December 31, 2022, the Company had gross U.S. federal and state research and development and other tax credit carryforwards of $0.3 million and $0.1 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2042 and 2037, respectively.

The Company accounts for uncertain tax positions pursuant to ASC 740,*Income Taxes*, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured at the largest amount of benefit that is more likely than not (determined by cumulative probability) of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. No interest and penalties related to uncertain tax positions were accrued at December 31, 2023 and December 31, 2022.

On December 22, 2017, the Tax Cuts and Jobs Act, or the TCJA, was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense qualified research and development expenditures. Taxpayers are now required to capitalize and amortize these costs over five years for research conducted within the United States or 15 years for research conducted abroad.

The following table sets forth a reconciliation of the beginning and ending amounts of unrecognized tax benefits, excluding the impact of interest and penalties, for the year ended December 31, 2023 (in thousands):

Unrecognized tax benefits at December 31, 2022	$	5,363
Decrease as a result of a lapse of the applicable statute of limitations		(5,363)
Unrecognized tax benefits at December 31, 2023	$	—

The Company does not expect unrecognized tax benefits to change significantly over the next twelve months. The full amount of unrecognized tax benefits would impact the effective rate, subject to valuation allowance considerations, if recognized.

9. Stockholders' equity

The Company had 3,750,000 shares authorized and 1,236,688 and 931,489 shares of common stock issued and outstanding as of December 31, 2023 and December 31, 2022, respectively, with a par value of $0.001 per share.

The Company had 10,000,000 shares authorized and 15,617 shares of preferred stock issued and outstanding as of December 31, 2023 and 2022. Preferred stock has a par value of $0.001 per share, and consists of the following tranches:

- Series A Convertible, 85 shares issued and outstanding at December 31, 2023 and 2022
- Series B Convertible, 4,026 shares issued and outstanding at December 31, 2023 and 2022
- Series C Convertible, 3,506 shares issued and outstanding at December 31, 2023 and 2022
- Series D Convertible, 3,000 shares issued and outstanding at December 31, 2023 and 2022
- Series E Convertible, 5,000 shares issued and outstanding at December 31, 2023 and 2022

Common Stock

Each share of the Company's common stock is entitled to one vote and all shares rank equally as to voting and other matters. Dividends may be declared and paid on the common stock from funds legally available therefore, if, as and when determined by the Board of Directors.

Preferred Stock

The Company has issued multiple series (Series A through E) of preferred stock to certain entities affiliated with Biotechnology Value Fund, L.P., or BVF. In each case, each share Preferred Stock is convertible into 13.34 shares of the Company's common stock (subject to adjustment as provided in the Certificate of Designation for each series) at any time at the option of the holder, provided that the holder is prohibited from converting the Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of Common Stock then issued and outstanding, or the Beneficial Ownership Limitation. The holder may reset the Beneficial Ownership Limitation to a higher or lower number, not to exceed 19.99% of the total number of common shares issued and outstanding immediately after giving effect to a conversion, upon providing written notice to the Company. Any such notice providing for an increase to the Beneficial Ownership Limitation will be effective 61 days after delivery to the Company.

Series A, Series B, Series C, Series D and Series E Preferred Stock rank senior to the Company's common stock; senior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as junior to the five series of Preferred Stock; in parity with each other and with any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as in parity with the existing five series of Preferred Stock; and junior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as senior to the existing five series of Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, subject to the rights of holders of, holders are entitled to receive a payment equal to $0.001 per share of Preferred Stock pursuant to the rights and preferences discussed above, plus an additional amount equal to any dividends declared but unpaid on such shares. However, if the assets of the Company are insufficient to comply with the preceding sentence, then all remaining assets of the Company shall be distributed ratably to holders of the shares of the existing five series of Preferred Stock.

For each series of Preferred Stock, the Company designated the requisite number of shares of its authorized and unissued preferred stock as a specific series of Preferred Stock and filed a Certificate of Designation with the Nevada Secretary of State.

Shares of Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Preferred Stock is required to amend the terms of the Certificate of Designation for each respective series of Preferred Stock. Holders of Preferred Stock are entitled to receive any dividends payable to holders of the Company's common stock subject to the rights and preferences discussed above, in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

Series A Preferred Stock

In June 2016, the Company entered into a securities purchase agreement for a private placement of the Company's securities with a select group of institutional investors, or the 2016 PIPE. The 2016 PIPE sale transaction, by the Company, consisted of 8,188,804 units at a price of $2.015 per unit for gross proceeds, to the Company, of approximately $16.5 million. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the private placement was approximately $15.3 million. In connection with the 2016 PIPE, the Company issued 40,323 shares of common stock and 4,963 shares of Series A Preferred Stock to the 2016 PIPE investors.

Series B Preferred Stock

On January 30, 2019, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which BVF agreed to exchange an aggregate of 62,500 shares of the Company's common stock owned by BVF for an aggregate of 5,000 shares of Series B Preferred Stock.

Series C and 2019 Private Placement

In November 2019, the Company entered into a securities purchase agreement for a private placement, or the Purchase Agreement with a select group of institutional investors, including lead investor BVF as well as existing and new investors, or Investors. The private placement consisted of 9,014,960 units, at a price of $3.55 per unit, or the Financing, for gross proceeds of approximately $32.0 million, and net proceeds to the Company of approximately $31.0 million. Each unit consists of (i) one share of the Company's common stock or 0.001 shares of non-voting convertible preferred stock, or Series C Preferred Shares, and together with the Common Shares, or Shares, and (ii) one immediately-exercisable warrant to purchase one share of the Company's common stock with an exercise price of $568.00, or Exercise Price.

If (i) the initial public disclosure of the phase 2a Study of elarekibep that includes the "p" value achieved for the primary endpoint of such study reveals top-line data on the primary efficacy endpoint in the phase 2a Study with a "p" value below 0.05 (i.e., $p < 0.05$) in at least one dose level; and (ii) the 10-day volume weighted average stock price commencing on the trading day immediately after the initial public disclosure is at least three percent more than the Exercise Price, ((i) and (ii), collectively, the "Performance Condition"), then the warrants will be exercisable for a period of 60 days from the date of the initial data disclosure and may only be exercised for cash. Otherwise, the warrants will be exercisable for a period of five years from the date of issuance, or Exercise Date. If the Performance Condition has not been met and the last reported sale price of the Company's common stock immediately prior to the Expiration Date was greater than the Exercise Price, then the warrants shall be automatically deemed exercised on a cashless basis on the Expiration Date.

Upon issuance, each Series C Preferred Share included an embedded beneficial conversion feature as the market price of the Company's common stock on the date of issuance of the Series C convertible Preferred Stock was $274.40 per share. As a result, the Company recorded the intrinsic value of the beneficial conversion feature of $2.8 million as a discount on the Series C convertible preferred stock at issuance. As the Series C Preferred Shares are immediately convertible upon issuance and do not include a stated redemption date, the discount was immediately accreted as a deemed dividend.

Series D Preferred Stock Conversion

On March 31, 2020, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which, on April 1, 2020, BVF exchanged an aggregate of 37,500 shares of the Company's common stock owned by BVF for an aggregate of 3,000 shares of Series D Preferred Stock.

Series E Preferred Stock Conversion

On May 20, 2021, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which, BVF exchanged an aggregate of 62,500 shares of the Company's common stock owned by BVF for an aggregate of 5,000 shares of Series E Preferred Stock.

Open Market Sales Agreement

In August 2021, the Company established an at-the-market program, or ATM Program, under a sales agreement with Jefferies LLC, pursuant to which the Company may offer and sell shares of its common stock, par value $0.001 per share, from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million. In November 2022, the sales agreement was amended to provide for an increase in the aggregate offering amount, such that under the ATM Program, as amended, the Company may offer and sell shares of its common stock, from time to time, up to an aggregate amount of gross sales proceeds of $75.0 million. The ATM Program, as amended, is offered under a shelf registration statement on Form S-3 that was filed with and declared effective by the SEC in August 2021. For the year ended December 31, 2023, the Company sold 0.3 million shares for gross proceeds of $20.3 million under the ATM Program at an average stock price of $67.07. For the year ended December 31, 2022, the Company sold 25,000 shares for gross proceeds of $7.2 million under the ATM Programs and the predecessor ATM program at an average stock price of $276.51.

As of the filing of this Annual Report on Form 10-K, the Company will be subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company's common stock held by non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of its common stock using its Form S-3, including under the ATM Program, until such time as its public float exceeds $75 million.

10. Net Loss per Share

Basic net loss per share is calculated by dividing net income (loss) by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, stock options, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

For the years ended December 31, 2023 and 2022, and as calculated using the treasury stock method, approximately 0.5 million and 0.5 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

11. Stock and Employee Benefit Plans

Employee, Director and Consultant Equity Incentive Plans

At the 2020 Annual Shareholder Meeting, held on June 23, 2020, the stockholders approved the 2020 Employee, Director and Consultant Equity Incentive Plan, or the 2020 Plan. The 2020 Plan originally permitted the Company to issue up to 43,750 shares of common stock pursuant to awards granted under the 2020 Plan. Upon approval of the 2020 Plan, the 2019 Employee, Director and Consultant Equity Incentive Plan, or the 2019 Plan, was terminated; all unissued options were canceled and no additional awards will be made thereunder. All outstanding awards under the 2019 Plan will remain in effect and any awards forfeited from the outstanding awards will be allocated back into the 2020 Plan. The 2020 Plan, similar to the 2019 Plan, provided for the grant of stock options, restricted and unrestricted stock awards, and other stock-based awards to employees of the Company, non-employee directors of the Company, and certain other consultants performing services for the Company as designated by either the Board of Directors or the compensation committee of the Board of Directors. At the 2021 Annual Meeting of Stockholders, held on June 25, 2021, the Company's stockholders approved the first amendment to the 2020 Plan to add 28,125 shares for issuance under the 2020 Plan, which increased the total permitted for issuance under the 2020 Plan to 71,875. At the 2022 Annual Meeting of Stockholders, held on June 22, 2022, the Company's stockholders approved the second amendment to the 2020 Plan to add an additional 37,500 shares for issuance under the 2020 Plan. At the 2023 Annual Meeting of Stockholders held on June 21, 2023, the Company's stockholders approved a third amendment to the 2020 Plan to add 75,000 shares of common stock for issuance under the 2020 Plan, which increased the total permitted for issuance under the 2020 Plan to 184,375. The 2020 Plan permits the Company to issue up to 184,375 shares reserved for issuance pursuant to the 2020 Plan and any additional shares which may be issued if awards outstanding under the Company's 2014, 2016, 2018 and 2019 Plans are canceled or expire.

The Company's stock options have a maximum term of 10 years from the date of grant. Stock options granted may be either incentive stock options or nonqualified stock options and the exercise price of stock options must be at least equal to the fair market value of the common stock on the date of grant. The Company's general policy is to issue shares of common stock upon the exercise of stock options.

The Company estimates the fair value of each stock award on the grant date using the Black-Scholes option-pricing model based on the following assumptions:

	Years Ended December 31,	
	2023	**2022**
Risk free interest rate	3.33% - 4.11%	1.43% - 3.39%
Expected term (in years)	5.5 - 5.73	5.5 - 5.73
Dividend yield	—	—
Expected volatility	79.5% - 98.6%	79.9% - 81.1%

The weighted-average fair value of the 46,677 and 38,498 options granted during the years ended December 31, 2023 and 2022 was $97.34 and $230.29, respectively. As of December 31, 2023, there were 116,060 shares available for future grant under the 2020 Plan.

The following table summarizes stock option activity for employees and non-employees:

	Number of Options	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual Life (in years)**	**Aggregate Intrinsic Value (in thousands)**
Outstanding, December 31, 2022	165,849	$ 256.93		$ —
Granted	46,677	97.34		—
Canceled/Forfeited	34,345	208.95		—
Outstanding, December 31, 2023	178,181	$ 224.37	5.90	$ —
Vested or expected to vest, December 31, 2023	178,181	$ 224.37	5.90	$ —
Exercisable, December 31, 2023	126,179	$ 257.26	4.75	$ —

Periodically, the Company grants inducement options, which are awards outside of stockholder-approved stock option plans, and which are awarded as an inducement material to the executive officers or other personnel entering senior leadership roles with the Company. The terms of inducement option awards were substantially the same as those issued under our 2020 Plan. These awards are excluded from the table above. The following table summarizes stock option activity for these inducement options (in thousands):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	3,750	$ 372.00		$ —
Granted	—	$ —		$ —
Canceled/Forfeited	—	$ —		$ —
Outstanding, December 31, 2023	3,750	$ 372.00	5.67	$ —
Vested or expected to vest, December 31, 2023	3,750	$ 372.00	5.67	$ —
Exercisable, December 31, 2023	3,750	$ 372.00	5.67	$ —

Employee Stock Purchase Plans

At the 2023 Annual Meeting of Stockholders, the Company's stockholders approved the 2023 Employee Stock Purchase Plan, or the 2023 ESPP, which replaces the former 2018 Employee Stock Purchase Plan, or 2018 ESPP. The 2023 ESPP provides eligible employees with the opportunity to purchase shares of the Company's common stock at a discount of 85% of the lower closing market price of the common stock at the beginning date or ending date of each purchase period, on a tax-favored basis, through regular payroll deductions in compliance with federal tax regulations. The Company has reserved 9,375 shares of common stock for issuance under the 2023 ESPP.

Total shares purchased under the 2023 ESPP and 2018 ESPP plan were 1,933 and 2,268 for the years ended December 31, 2023 and 2022, respectively.

Total Stock-based Compensation Expense

Total stock-based compensation expense is recorded in operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Research and development	$ 1,190	$ 1,905
General and administrative	2,159	2,497
Total stock-based compensation	$ 3,349	$ 4,402

As of December 31, 2023, the total unrecognized compensation cost related to all non-vested awards was $4.3 million. The unrecognized compensation cost would be recognized over a remaining weighted-average period of 2.24 years.

12. License Agreement

TUM License

The Company and the Technical University of Munich, or TUM, initiated discussions in the second quarter of 2018 to clarify, expand and restructure the research and licensing agreement with TUM, the TUM License, including the parties' obligations under the TUM License. The TUM License assigns or exclusively licenses to the Company certain intellectual property related to the Company's Anticalin platform technology. The parties' discussions relate to revised commercial terms and to re-initiating additional collaborations between faculty at TUM and Pieris. While an amended and restated license agreement has not yet been completed, the Company may enter into an amendment reflecting the parties discussions. These discussions may also lead to an increase in the Company's collaborative research activities with TUM.

13. Leases

In August 2015, the Company entered into a sublease to lease approximately 3,950 square feet in Boston, Massachusetts, which expired on December 31, 2022. The Company did not extend the sublease. The Company generally conducts its operational functions in the United States remotely.

In October 2018, Pieris Pharmaceuticals GmbH entered into a lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Pieris GmbH moved its operations to the Hallbergmoos facility in February 2020. The Hallbergmoos Lease was subsequently amended in May 2019 and February 2020. The Hallbergmoos Lease, as amended, provided an initial rental term of 12.5 years, and a rental area of approximately 105,000 square feet.

In December 2023, Pieris Pharmaceuticals GmbH entered into an agreement to terminate the Hallbermoos Lease, or the Lease Termination Agreement. Under the terms of the Lease Termination Agreement, Pieris Pharmaceuticals GmbH terminated the Hallbergmoos Lease in exchange for a termination fee of approximately €9.7 million, and vacated the majority of the premises by December 31, 2023, while continuing to occupy, through June 2024, a limited portion of the office space and using another portion of the former lab space to house its assets being held for sale.

Cash paid for amounts included in the measurement of the lease liabilities were $2.2 million and $2.4 million for the years ended December 31, 2023 and 2022, respectively, all of which were incurred prior to the lease termination.

The Hallbergmoos Lease included $11.5 million of tenant improvements allowance for normal tenant improvements which was incurred prior to commencing the lease. The Company capitalized the leasehold incentives which were included in Property and equipment, net on the Consolidated Balance Sheet and were amortized on a straight-line basis over the shorter of the useful life or the remaining lease term. The leasehold improvement were subsequently fully impaired in the third quarter of 2023.

The following table summarizes operating lease costs included in operating expenses (in thousands):

	Year Ended December 31,	
	2023	**2022**
Operating lease costs	$ 1,169	$ 1,356
Variable lease costs (1)	679	737
Total lease cost	$ 1,848	$ 2,093

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes, utilities and other costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage. These costs also included costs associated with increases rent expense based on CPI.

14. Subsequent Event

The accompanying consolidated financial statements reflect the 1-for-80 reverse split of the Company's common stock that was approved by the Company's Board of Directors and made effective on April 22, 2024. All share and per share information herein that relates to common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

FINANCIAL STATEMENTS (UNAUDITED)

Palvella Therapeutics, Inc.
For the Quarterly Period Ended September 30, 2024

PALVELLA THERAPEUTICS, INC.

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PALVELLA THERAPEUTICS, INC.

BALANCE SHEETS

(in thousands, except share and per share amounts)

	September 30, 2024 *(unaudited)*	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 14,207	$ 7,350
Deferred transaction costs	1,673	—
Prepaid expenses and other current assets	441	198
Total current assets	16,321	7,548
Total assets	$ 16,321	$ 7,548
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,130	$ 936
Accrued expenses and other current liabilities	4,505	1,424
Total current liabilities	7,635	2,360
Royalty agreement liability	10,819	8,054
Derivative liabilities – royalty agreement	1,418	1,014
Convertible notes payable	13,250	—
Total liabilities	33,122	11,428
Commitments and contingencies (Note 10)		
Convertible preferred stock, $0.00001 par value; 20,655,895 shares authorized; 15,360,787 shares issued and outstanding at September 30, 2024 and December 31, 2023; aggregate liquidation value of $66,063 at September 30, 2024	70,603	70,603
Stockholders' deficit:		
Common stock, $0.00001 par value; 29,000,000 (25,500,000 voting and 3,500,000 non-voting) shares authorized; 5,720,009 (5,050,000 voting and 670,009 non-voting) shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	2,380	1,818
Accumulated deficit	(89,784)	(76,301)
Total stockholders' deficit	(87,404)	(74,483)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 16,321	$ 7,548

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS (UNAUDITED)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 3,182	$ 1,096	$ 5,608	$ 8,094
General and administrative	1,880	457	4,121	2,359
Total operating expenses	5,062	1,553	9,729	10,453
Operating loss	(5,062)	(1,553)	(9,729)	(10,453)
Other (expense) income:				
Interest (expense) income - royalty agreement	(1,017)	(1,298)	(2,764)	7,407
Interest expense – convertible notes payable	(220)	-	(249)	-
Fair value adjustments on derivative liabilities - royalty agreement	(75)	(52)	(404)	541
Fair value adjustments on convertible notes payable	(568)	-	(568)	-
Other (expense) income, net	167	71	231	657
Net loss	$ (6,775)	$ (2,832)	$ (13,483)	$ (1,848)
Net loss per share:				
Basic and diluted	$ (1.22)	$ (0.53)	$ (2.46)	$ (0.42)
Weighted-average shares used in computing net loss per share:				
Basic and diluted	5,720,009	5,720,009	5,720,009	5,720,009

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (UNAUDITED)

(in thousands, except share amounts)

For the Three Months Ended September 30, 2024 and 2023

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at June 30, 2023	15,360,787	$ 70,603	5,720,009	$ —	$ 1,515	$ (94,008)	$ (92,493)
Stock-based compensation	—	—	—	—	154	—	154
Net loss	—	—	—	—	—	(2,832)	(2,832)
Balance at September 30, 2023	15,360,787	$ 70,603	5,720,009	$ —	$ 1,669	$ (96,840)	$ (95,171)
Balance at June 30, 2024	15,360,787	$ 70,603	5,720,009	$ —	$ 2,181	$ (83,009)	$ (80,828)
Stock-based compensation	—	—	—	—	199	—	199
Net loss	—	—	—	—	—	(6,775)	(6,775)
Balance at September 30, 2024	15,360,787	$ 70,603	5,720,009	$ —	$ 2,380	$ (89,784)	$ (87,404)

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (UNAUDITED)

(in thousands, except share amounts)

For the Nine Months Ended September 30, 2024 and 2023

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2023	15,360,787	$ 70,603	5,720,009	$ —	$ 1,215	$ (94,992)	$ (93,777)
Stock-based compensation	—	—	—	—	454	—	454
Net loss	—	—	—	—	—	(1,848)	(1,848)
Balance at September 30, 2023	15,360,787	$ 70,603	5,720,009	$ —	$ 1,669	$ (96,840)	$ (95,171)
Balance at January 1, 2024	15,360,787	$ 70,603	5,720,009	$ —	$ 1,818	$ (76,301)	$ (74,483)
Stock-based compensation	—	—	—	—	562	—	562
Net loss	—	—	—	—	—	(13,483)	(13,483)
Balance at September 30, 2024	15,360,787	$ 70,603	5,720,009	$ —	$ 2,380	$ (89,784)	$ (87,404)

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (13,483)	$ (1,848)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest (income) expense – royalty agreement	2,764	(7,407)
Non-cash interest expense – convertible notes payable	249	—
Change in fair value of derivative liabilities - royalty agreement	404	(541)
Change in fair value of convertible notes payable	568	—
Stock-based compensation	562	454
Costs to issue convertible notes payable	129	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(243)	290
Accounts payable	2,195	(1,184)
Accrued expenses and other current liabilities	1,408	(1,040)
Net cash used in operating activities	(5,447)	(11,276)
Cash flows from financing activities		
Proceeds from the issuance of convertible notes payable	12,433	—
Costs to issue convertible notes payable	(129)	—
Net cash provided by financing activities	12,304	—
Net increase (decrease) in cash and cash equivalents	6,857	(11,276)
Cash and cash equivalents at beginning of year	7,350	16,053
Cash and cash equivalents at end of period	$ 14,207	$ 4,777
Supplementary schedule of non-cash financing activities:		
Deferred transaction costs, accrued but not paid	$ 1,673	$ —

The accompanying notes are an integral part of these financial statements

1. Description of Business, Organization and Liquidity

Business Risks and Liquidity

Palvella Therapeutics, Inc. (the "Company") is a late clinical-stage biopharmaceutical company committed to serving individuals suffering from serious, rare genetic skin diseases without approved therapies. The Company's lead product candidate, QTORIN 3.9% rapamycin anhydrous gel ("QTORIN rapamycin"), is based on the Company's patented QTORIN platform. QTORIN rapamycin is in clinical development for two rare genetic skin disorders. Since inception, the Company has devoted substantially all of its time to identifying, researching and conducting preclinical and clinical activities for its product candidates, acquiring and developing its platform technology, organizing and staffing the Company, business planning, raising capital and establishing its intellectual property portfolio. The Company's principal executive offices are located in Wayne, Pennsylvania.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the three and nine months ended September 30, 2024, the Company reported net loss of $6.8 million and $13.5 million, respectively, and net cash used in operating activities of $5.4 million. At September 30, 2024, the Company had an accumulated deficit of $89.8 million.

The Company has financed its operations to date primarily through the sale of its convertible preferred stock, funding received under a royalty agreement, and entering into a convertible note purchase agreement that are convertible into the Company's common stock based on certain conditions and events. $13.2 million of the convertible note purchase agreements has been issued as of September 30, 2024, which includes $12.4 million in principal and $0.8 million of accrued interest and other expense related to the fair value adjustment of the convertible notes. An additional $6.0 million in convertible notes has been issued in total through December 13, 2024. Management does not expect to generate commercial revenue or operating cash flows for at least the next several years. The Company's ability to continue as a going concern in the near term is largely dependent on its ability to obtain additional sources of financing in order to fund operating expenses, complete development of its product candidates, obtain regulatory approvals, launch, and commercialize its product candidates, and continue research and development programs. Assuming no additional fund raising, the Company's forecasted cash required to fund operations indicates that the Company does have sufficient funds to support operations through the one-year period from the issuance date of these financial statements. Accordingly, there is no doubt about the Company's ability to continue as a going concern within one year after the date that these financial statements are issued. In December 2024, the Company closed the merger receiving $11.4 million of cash from the public company and an additional $66.0 million from the closing of the PIPE, $60.0 million from PIPE investors and $6.0 million received from convertible notes. The total PIPE was $78.4 million in total cash, of which $18.4 million was received under convertible notes, and $60.0 million received at the closing of the PIPE.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts of classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP") for interim reporting. Any references in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Accordingly, these interim Financial Statements do not include all disclosures required by U.S. GAAP for annual financial statements pursuant to the rules and regulations of the U.S. Securities and Exchange Commission, or SEC. In management's opinion, the unaudited interim Financial Statements have been prepared on the same basis as the annual financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2024, the Company's results of operations for the three and nine months ended September 30, 2024 and 2023, and cash flows for the nine months ended September 30, 2024 and 2023. The results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the full fiscal year or any other future interim or annual periods.

The information contained within the unaudited interim financial statements should be read in conjunction with the audited financial statements and accompanying notes as of and for the year ended December 31, 2023.

Use of estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process and actual results could differ materially from those estimates.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company holds all cash at two accredited financial institutions in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company is dependent on contract manufacturing organizations ("CMOs") to supply products for research and development of its product candidates, including pre-clinical and clinical studies, and for commercialization of its product candidates, if approved. The Company's development programs could be adversely affected by any significant interruption in its CMOs' operations or by a significant interruption in the supply of active pharmaceutical ingredients and other components.

Products developed by the Company require approval from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's product candidates will receive the necessary approvals. If the Company is denied approvals, approvals are delayed, or it is unable to maintain approvals received, such events could have a materially adverse impact on the Company.

Cash and cash equivalents

Cash and cash equivalents are held in accounts at two independent financial institutions. Cash equivalents are defined as money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.

- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

At September 30, 2024 and December 31, 2023, the carrying amounts of financial instruments, which include cash and cash equivalents, accounts payable, and accrued expenses and other liabilities, approximate their fair value due to their short maturities. The Company records its derivative liabilities and convertible notes payable at fair value. At September 30, 2024 and December 31, 2023, the fair value of the royalty agreement liability, which is based on Level 3 inputs (including probability-weighted cash flow estimates of the Company's potential future royalty payments and a weighted-average cost of capital of 24.0% and 24.5%, respectively) is approximately $11.9 million and $8.0 million, respectively.

Derivative instruments

The Company has milestone payments which may be required in connection with the royalty agreement (see Note 4) that were determined to be derivative liabilities. The valuation of the derivative liabilities is based on unobservable inputs and, therefore, represent Level 3 financial liabilities. The fair value of the derivative liabilities – royalty agreement was calculated using the present value of the potential payments using a weighted-average cost of capital and an assessment of the probability of the achievement of the milestones as well as an assessment of the timing of the potential milestone payments.

The derivative liabilities – royalty agreement was initially recorded at fair value, with gains and losses arising for changes in fair value of the derivative liabilities – royalty agreement recognized within the statements of operations as fair value adjustments on the derivative liabilities at each financial reporting period.

Convertible Notes

The fair value of the Convertible Notes was based on a probability-weighted expected return model ("PWERM"), which represents Level 3 measurements. The valuation utilized unobservable inputs, including estimates of the probability and timing of future commercialization of products not yet approved by the FDA or other regulatory agencies. Other significant assumptions include the discount rate, the fair value of our common stock, volatility, probability of the Convertible Notes being held to maturity, the probabilities of certain exit events, including a qualified financing, non-qualified financing, or corporate transaction.

As permitted under FASB ASC Topic 825, Financial Instruments ("ASC 825"), the Company elected the fair value option to account for its September 2024 convertible notes (collectively, the "Convertible Notes"). In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Statement of Operations. As a result of applying the fair value option, direct costs and fees of $0.1 million related to the convertible notes were expensed as incurred and were not deferred. See Note 6.

Research and development expenses

Research and development costs are charged to expense as incurred. Research and development expenses include, among other costs, salaries and benefits of scientific personnel and the external cost of producing and testing the clinical material for clinical trials.

The Company has entered various research and development and clinical trial-related contracts. The Company defers and capitalizes prepaid nonrefundable advance research and development payments to third parties for goods and services to be used in future research and development activities and recognizes to research and development expense over the period that the research and development activities are performed or the services are provided. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and clinical trial costs. When determining the accruals, at the end of a reporting period, the Company analyzes progress of its studies and clinical trials, including the phase or completion of events, invoices received and contracted costs. Actual results could differ from the Company's estimates.

Stock-based compensation

The Company measures all stock options and other stock-based awards granted to employees, directors, consultants, and other nonemployees based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period on a straight-line basis, which is generally the vesting period of the respective award. The Company recognizes forfeitures at the time forfeitures occur.

The Company classifies stock-based compensation expense in its statements of operations in the same way the payroll costs or service payments are classified for the related stock-based award recipient.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model ("Black-Scholes"). Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Government Grants

The Company recognizes grants from governmental agencies when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received. The Company evaluates the conditions of each grant as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant will be received as a result of meeting the necessary conditions. Grants are recognized in the consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Grant income is recorded as a reduction of research and development costs in the statements of operations. In September 2024, the Company received a grant award notice from the Department of Health and Human Services in connection with its ongoing Phase 3 clinical trial, SELVA, whereby the Company expects to receive approximately $0.5 million through August 2025. For the quarter ended September 30, 2024, the Company recognized $14,000 of grant income as a reduction to research and development costs in the statements of operations.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all the tax benefits will not be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrued liability for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income taxes.

Related party transactions

The Company's board of directors reviews and approves transactions with directors, officers, and holders of 5% or more of its voting securities and their affiliates, each a related party. The material facts as to the related party's relationship or interest in the transaction are disclosed to its board of directors prior to their consideration of such transaction, and the transaction is not considered approved by its board of directors unless a majority of the directors who are not interested in the transaction approve the transaction.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

Net (loss) income per share

The Company's convertible preferred stock are participating securities. Accordingly, in any period in which the Company reports net income, basic earnings per share is computed using the "two-class" method which includes the weighted- average number of shares of common stock outstanding during the period and other securities that participate in dividends (a participating security). During the periods where the Company incurs net losses, the Company allocates no loss to participating securities because these securities have no contractual obligation to share in the losses of the Company.

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For the three and nine months ended September 30, 2024 and 2023 basic and diluted net loss per share are the same.

Recently issued accounting standards

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 for public companies and December 15, 2025 for private companies and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of the ASU on the income tax disclosures within its financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures which requires that a public entity provide additional segment disclosures on an interim and annual basis. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements, unless impracticable. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. For public companies the ASU is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of the adoption on the Company's financial statements.

3. Fair Value Measurements

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	September 30, 2024			
	Level 1	Level 2	Level 3	Total
Current assets:				
Money market funds	$ 13,889	$ —	$ —	$ 13,889
Total assets measured at fair value	$ 13,889	$ —	$ —	$ 13,889
Liabilities:				
Derivative liabilities - royalty agreement	$ —	$ —	$ 1,418	$ 1,418
Convertible notes payable	—	—	13,250	13,250
Total liabilities measured at fair value	$ —	$ —	$ 14,668	$ 14,668

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Current assets:				
Money market funds	$ 7,203	$ —	$ —	$ 7,203
Total assets measured at fair value	$ 7,203	$ —	$ —	$ 7,203
Liabilities:				
Derivative liabilities - royalty agreement	$ —	$ —	$ 1,014	$ 1,014
Total liabilities measured at fair value	$ —	$ —	$ 1,014	$ 1,014

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds is based on quoted prices in active markets for identical securities. This approach results in a classification of these securities as Level 1 of the fair value hierarchy. Money market funds are cash equivalents and are included in cash and cash equivalents on the Company's balance sheet as of September 30, 2024 and December 31, 2023.

The Company measures the Convertible Notes and warrant liabilities at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. These valuations use assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the Convertible Notes and warrant liabilities related to updated assumptions and estimates are recognized within the statements of operations. There were no changes in instrument-specific credit risk for the Notes for the periods ended September 30, 2024.

The fair value of the Convertible Notes and warrant liabilities may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of outcomes used to estimate the fair value of the liabilities. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The key assumptions used to determine the fair value of the derivative liabilities – royalty agreement at September 30, 2024 and December 31, 2023 are as follows:

	September 30, 2024	December 31, 2023
Discount rate	24.0%	25.0%
Probability rate of achieving FDA approval of a product	56.6%	50.0%
Expected term to FDA regulatory approval of a product (in years)	2.67	3.50

The following assumptions were used in determining the fair value of the Convertible Notes as of September 30, 2024:

	September 30, 2024
Risk-free interest rate	4.40%
Volatility	77.50%
Dividend yield	0.00%
Probability-weighted remaining term (years)	0.5
Stock price	$ 3.67

The following tables provide reconciliations of the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at September 30, 2024 (in thousands):

Derivative Liabilities – Royalty Agreement

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024
Balance, beginning of period	$ 1,343	$ 1,014
Fair value adjustments	75	404
Balance, end of the period	$ 1,418	$ 1,418

Convertible Notes Payable

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024
Balance, beginning of period	$ 10,029	$ -
Initial fair value at issuance	-	10,000
Issuance of convertible notes during the period	2,433	2,433
Accrued interest expense	220	249
Fair value adjustments	568	568
Balance, end of the period	$ 13,250	$ 13,250

4. Strategic Agreements

Ligand Development Funding Agreement

In December 2018, the Company entered into the Ligand Agreement with Ligand, whereby Ligand agreed to make a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. As partial consideration for the one-time payment, the Company granted Ligand the right to receive up to $8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by the Company related to QTORIN rapamycin for the treatment of any and all indications. In addition, the Company agreed to pay to Ligand tiered royalties from 5.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. On a licensed product-by-licensed product and country-by-country basis, the royalty period is from the date of first commercial sale of such licensed product in a country until the latest of (i) the expiration of the last valid claim within the licensed patent rights covering such licensed product in the country in which such licensed product is made, used or sold, (ii) the expiration of the regulatory exclusivity term conferred by the applicable regulatory authority in such country with respect to such licensed product, and (iii) the fifteenth anniversary of the first commercial sale of such licensed product in such country. In certain circumstances, the agreement allowed the Company to reduce the royalty rates under the Ligand Agreement by making payments ("Royalty Buy Down Payments"). Specifically, once the Company has made royalty payments to Ligand equal to certain specified amounts in the mid eight figures, the Company has the option to make Royalty Buy Down Payments at any time during the remainder of the term of the Ligand Agreement to reduce its certain royalty tier percentages on annual worldwide net sales of any products by one or two percentage points. Such Royalty Buy Down Payments range in size from the low seven figures to the low eight figures.

Ligand may terminate the agreement for any or no reason upon a 90-day notice to the Company. Ligand may also terminate the agreement for cause in connection with a material breach that the Company does not cure within a certain period of time.

The total amount of potential future milestone payments remaining under the arrangement were $5.0 million as of September 30, 2024 and December 31, 2023. The potential future milestone payments represent derivative liabilities with a fair value of $1.4 million and $1.0 million as of September 30, 2024 and December 31, 2023, respectively, which are classified as derivative liabilities – royalty agreement on the accompanying balance sheets. See Note 3 for fair value measurements.

The Company's obligation to pay tiered royalties under the Ligand Agreement was determined to be a debt instrument based on the likelihood of repaying the amounts provided to fund the development of QTORIN rapamycin and that the Company has significant continuing involvement in the generation of the cash flows potentially due to Ligand. This obligation is reflected as royalty agreement liability which is classified as a long-term liability on the accompanying balance sheets. Interest expense with respect to the royalty agreement liability is determined using the effective interest method based upon probability-adjusted cash flow estimates of the Company's potential future royalty payments under the Ligand Agreement, yielding an effective interest rate of 39.9% and 20.2% for the three and nine months ended September 30, 2024 and 2023, respectively. Changes in these estimates impact the amount of interest expense recognized through the accompanying statements of operations. During the second quarter 2023, the Company received data from certain of its clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization resulting in a significant reduction in the future royalty agreement liability. In the second quarter of 2024, the Company received data that adjusted the projected net product sales related to QTORIN rapamycin resulting in an increase to the future royalty agreement liability. The Company incurred non-cash interest expense of $1.0 million and $1.3 million for the three months ended September 30, 2024 and 2023, respectively. The Company incurred non-cash interest expense of $2.8 million for the nine months ended September 30, 2024 and non-cash interest income of $7.4 million for the nine months ended September 30, 2023. Interest (expense) income is a component of the royalty agreement liability on the accompanying balance sheets.

In November 2023, the Ligand Agreement was amended (the "Amended Ligand Agreement"), whereby Ligand paid the Company an additional $5.0 million in return for an increase in the future tiered royalties to 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. The Royalty Buy Down Payments, and the associated rate modifications, in the original agreement were eliminated as part of the amendment. The Company determined that the original Ligand Agreement was extinguished with the newly Amended Ligand Agreement recorded at the estimated fair value of the royalty agreement liability on the date of the amendment. This resulted in a one-time, non-cash gain on extinguishment of approximately $23.1 million for the quarter ended December 31, 2023.

The Ligand Agreement requires the Company to make certain estimates and assumptions about the future development, FDA approval, commercialization, and net sales of any product containing QTORIN rapamycin. These estimates and assumptions are subject to significant variability and are thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as the Company develops and commercializes products containing QTORIN rapamycin that may result in future adjustments to the royalty agreement liability, the derivative liabilities, and the accretion of interest expense.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Professional fees	$ 2,343	$ 960
Compensation expense	1,462	175
Research and development expenses	418	120
Other	282	169
Total accrued expenses and other current liabilities	$ 4,505	$ 1,424

6. Convertible Notes Payable

To facilitate the ongoing operations of the Company, the Company entered into the following Convertible Notes during the periods ended September 30, 2024:

	Issuance Date	Original Issuance Amount	Maturity Date	Interest Rate	Fair Value as of September 30, 2024
Note 1	6/4/2024	$ 5,000,000	6/6/2027	SOFR + 2%	$ 5,348,754
Note 2	6/26/2024	2,500,000	6/6/2027	SOFR + 2%	2,662,842
Note 3	6/26/2024	2,500,000	6/6/2027	SOFR + 2%	2,662,842
Note 4	7/17/2024	50,000	6/6/2027	SOFR + 2%	53,037
Note 5	7/17/2024	50,000	6/6/2027	SOFR + 2%	53,036
Note 6	7/19/2024	20,000	6/6/2027	SOFR + 2%	159,047
Note 7	7/19/2024	143,000	6/6/2027	SOFR + 2%	151,624
Note 8	7/19/2024	100,000	6/6/2027	SOFR + 2%	106,031
Note 9	7/19/2024	70,000	6/6/2027	SOFR + 2%	74,222
Note 10	7/19/2024	150,000	6/6/2027	SOFR + 2%	21,206
Note 11	7/22/2024	700,000	6/6/2027	SOFR + 2%	741,776
Note 12	7/22/2024	500,000	6/6/2027	SOFR + 2%	529,840
Note 13	7/22/2024	150,000	6/6/2027	SOFR + 2%	158,952
Note 14	8/20/2024	500,000	6/6/2027	SOFR + 2%	526,791
		$ 12,433,000			$ 13,250,000

Total interest expense incurred on the Convertible Notes during the nine months ended September 30, 2024 totaled $249,000. As of and for the three and nine months ended September 30, 2024, the interest rate for the Convertible Notes was 6.80%.

Upon a Qualified Financing, defined as either the earlier to occur of a) issuance of shares of preferred stock resulting in aggregate gross proceeds of at least $20,000,000 or b) an initial public offering, in each case on or before the maturity date, the principal and accrued interest on the Convertible Notes shall automatically convert into shares of the Company. In the case of the Qualified Financing being an issuance of preferred stock resulting in aggregate gross proceeds of at least $20,000,000, the Convertible Notes shall convert into shares of preferred stock having identical rights, privileges, preferences and restrictions as those issued to the investors in the Qualified Financing. In the case of the Qualified Financing being an initial public offering, the Convertible Notes shall convert into shares of common stock.

The Qualified Financing Conversion Price is equal to the lesser of (a) 80% of the price paid per share by the investors in the Qualified Financing or (b) the price per share as calculated by dividing $126,188,357 by the number of shares of common stock outstanding on an as-converted basis immediately prior to the Qualified Financing. If the Company consummates a reverse merger within 12 months of the issuance date, then the Qualified Financing Conversion Price shall be equal to the lowest cash price per share paid by the purchasers of the equity securities in connection with the private investment in public entity (the "PIPE") or other related financing transaction consummated concurrently with the reverse merger.

Upon a Non-Qualified Financing, defined as any issuance of preferred stock to investors on or before the maturity date with the purpose of raising capital that does not meet the definition of a Qualified Financing, the holders of the Convertible Notes have the option to convert into shares of preferred stock having identical rights, privileges, preferences and restrictions as those issued to the investors in the Non-Qualified Financing.

The Non-Qualified Financing Conversion Price is equal to the lesser of (a) 80% of the price paid per share by the investors in the Non-Qualified Financing or (b) the price per share as calculated by dividing $126,188,357 by the number of shares of common stock outstanding on an as-converted basis immediately prior to the Non-Qualified Financing.

Upon a Corporate Transaction, as defined as a) the closing of the sale, transfer, or other disposition of all or substantially all of the Company's assets, b) the consummation of a merger with or into another entity (except for a reverse merger), or c) a liquidation or dissolution of the company, the holders will receive the greater of 1) 1.5 times the outstanding principal and accrued interest, 2) the amount the holders would have been entitled to receive had the outstanding principal and accrued interest been converted into shares of common stock at a price per share as calculated by dividing $126,188,357 by the number of shares outstanding on an as-converted basis immediately prior to the Corporate Transaction or 3) the amount the holders would have been entitled to receive had the outstanding principal and accrued interest been converted into shares of common stock immediately prior to the Corporate Transaction, at a price per share equal to 80% of the cash price per share paid or valued by the counterparty to the Company in a Corporate Transaction.

If the shares are neither repaid nor converted in connection with a Qualified Financing, Non-Qualified Financing, or Corporate Transaction, the outstanding principal and accrued interest of the Convertible Notes shall be due and payable within 30 days of the earlier of a) the date the Company receives approval of a new drug Application (NDA) by the United States Food and Drug Administration of QTORIN rapamycin b) September 6, 2027 or c) an event of default.

7. Convertible Preferred Stock

The Company amended and restated its certificate of incorporation (as amended, the "Amended Certificate") such that it is authorized to issue 29,000,000 shares of common stock (25,500,000 voting and 3,500,000 non-voting) and 20,655,895 shares of preferred stock, with 2,241,903 shares designated as Series A-1 Convertible Preferred stock ("Series A-1 Preferred"), 1,240,134 shares designated as Series A-2 Convertible Preferred stock ("Series A-2 Preferred"), 1,533,528 shares designated as Series B Convertible Preferred stock ("Series B Preferred"), 8,509,995 shares designated as Series C Convertible Preferred stock ("Series C Preferred") and 7,130,335 shares designated as Series D Preferred.

The following table summarizes outstanding convertible preferred stock (in thousands, except share and per share amounts):

	September 30, 2024 and December 31, 2023			September 30, 2024
	Original Issue Price Per Share	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference
Series A-1 Preferred	$ 1.31	2,241,903	2,241,903	$ 2,937
Series A-2 Preferred	$ 1.64	1,240,134	1,240,134	2,034
Series B Preferred	$ 3.19	1,533,528	1,533,528	4,892
Series C Preferred	$ 5.29	8,509,995	8,509,995	45,000
Series D Preferred	$ 5.29	7,130,335	1,835,227	11,200
		20,655,895	15,360,787	$ 66,063

The rights and preferences of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred, Series C Preferred and Series D Preferred, collectively Preferred Stock, under the Amended Certificate are as follows:

Dividends

The Series D Preferred holders, in preference to holders of any other series of the Company's stock, are entitled to cumulative dividends in an amount in cash equal to 8% of the applicable Series D Preferred original issue price of $5.29 per annum on each outstanding share of such Series D Preferred calculated from the date of issuance of such share, if and when declared by the Company's board of directors. The Series C Preferred holders, in preference to holders of any other series of the Company's stock other than the Series D Preferred, are entitled to non-cumulative dividends in an amount in cash equal to 8% of the applicable Series C Preferred original issue price of $5.29 per annum on each outstanding share of such Series C Preferred calculated from the date of issuance of such share, if and when declared by the Company's board of directors. The holders of Preferred Stock and Common Stock are entitled to participate in the distribution of the dividend as they would have received if all outstanding shares of Preferred Stock had been converted into common stock on the date of such event, after all holders of the Series D Preferred and the Series C Preferred have received such dividend in full. No dividends were declared or paid as of September 30, 2024. The Series D Preferred cumulative preferred stock dividends in arrears were approximately $1.5 million and $0.8 million as of September 30, 2024 and December 31, 2023, respectively.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of the Series D Preferred shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of Series D Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred, Series C Preferred and Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price plus and accrued but unpaid cumulative dividends, or (ii) such amount per share as would have been payable had all shares of Series D Preferred been converted into Common Stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event ("Series D Liquidation Amount").

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of the Series C Preferred shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of Series C Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred and Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price, or (ii) such amount per share as would have been payable had all shares of Series C Preferred been converted into Common Stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event ("Series C Liquidation Amount").

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, after payment in full of the Series D Liquidation Amount to the holders of Series D Preferred and the Series C Liquidation Amount to the holders of the Series C Preferred, holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price, or (ii) such amount per share as would have been payable had all shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, been converted into common stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event. If upon any such liquidation, dissolution, or winding up of the Company or deemed liquidation event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, the full amount to which they shall be entitled to the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Voting

The holders of outstanding shares of Preferred Stock are entitled to vote on all matters and shall be entitled to vote based on the number of shares of common stock into which each share of the preferred stock is convertible.

Redemption

Preferred Stock is not subject to mandatory redemption. The Preferred Stock is subject to redemption under certain deemed liquidation events not solely within the control of the Company, as defined, and as such are considered contingently redeemable for accounting purposes and are classified as temporary equity in the Company's balance sheets. As a result, the Preferred Stock is not currently redeemable and the Company has determined that the Preferred Stock is not considered probable to become redeemable.

Conversion

Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (a) the applicable original issue price by (b) the applicable conversion price in effect at the time of conversion.

Preferred Stock automatically converts upon the closing of a firm commitment underwritten initial public offering of common stock, in which the price per share is at least two times the Series D original issue price, subject to adjustment, resulting in gross proceeds of at least $50.0 million to the Company.

Preferred Stock	Preferred Conversion Price to Common Stock
Series A-1 Preferred	$ 1.31
Series A-2 Preferred	$ 1.64
Series B Preferred	$ 3.19
Series C Preferred	$ 5.29
Series D Preferred	$ 5.29

For Preferred Stock, the preferred conversion price and the rate at which applicable shares may be converted is subject to adjustment upon the occurrence of certain events. As of September 30, 2024 and December 31, 2023, the effective conversion ratio for all Preferred Stock is one for one.

8. 2019 Equity Incentive Plan

In March 2019, the Company adopted the 2019 Equity Incentive Plan (the "Plan"), which provides employees, consultants and advisors, and non-employee members of the Board of Directors and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options, and stock awards. In March 2024, the Company amended the 2019 Plan to include an additional 1,171,768 shares available for awards under the Plan. A total of 2,782,809 shares of the Company's non-voting common stock may be issued for grants under the Plan. As of September 30, 2024, there were 2,149,138 options granted and 633,671 were available for grant.

For incentive stock options and non-statutory stock options, the option exercise price may not be less than 100% of the estimated fair value on the date of grant. Options granted to employees typically vest over a four-year period but may be granted with different vesting terms. The options expire ten years from the grant date.

A summary of activity under the Plan for the nine months ended September 30, 2024 as follows:

	Common Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding at December 31, 2023	1,581,041	$ 2.72	7.3
Granted	568,097	2.33	
Exercised	—		
Forfeited / Cancelled	—		
Outstanding at September 30, 2024	2,149,138	$ 2.62	7.4
Exercisable at September 30, 2024	1,287,990	$ 2.61	6.2

The aggregate intrinsic value for both options outstanding and options exercisable as of September 30, 2024 was $69,000.

During the three months ended September 30, 2024 and 2023, the Company recognized $199,000 and $154,000, respectively, of stock-based compensation expense, of which $52,000 and $13,000, respectively, was recorded as general and administrative expense and $147,000 and $141,000, respectively, was recorded as research and development expense in the accompanying statements of operations.

During the nine months ended September 30, 2024 and 2023, the Company recognized $562,000 and $454,000, respectively, of stock-based compensation expense, of which $126,000 and $42,000, respectively, was recorded as general and administrative expense and $436,000 and $412,000, respectively, was recorded as research and development expense in the accompanying statements of operations.

As of September 30, 2024, there was approximately $1.6 million of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average service period of 3.0 years.

9. Income Taxes

The Company recorded no provision for income taxes for both the periods ended September 30, 2024 and 2023.

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOLs. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized. As such, there is a full valuation allowance against the net deferred tax assets as of September 30, 2024 and December 31, 2023.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of September 30, 2024 and December 31, 2023, the Company reported no liabilities for unrecognized tax benefits along with no related interest and penalty exposure as accrued income tax on the accompanying balance sheets. Income tax returns for the tax years 2020 and later remain subject to examination by the taxing authority jurisdictions.

10. Commitments and Contingencies

Lease

The Company leases office space in Wayne, Pennsylvania, under a lease agreement, as amended, expiring on October 31, 2025 that had an initial term of less than 12 months. The minimum lease payments due under this lease are as follows as of September 30, 2024 (in thousands):

Year ended December 31,	
2024	$ 20
2025	67
Total future minimum payments	$ 87

Rent expense recorded during the three months ended September 30, 2024 and 2023 was $20,000. Rent expense recorded during the nine months ended September 30, 2024, and 2023 was $60,000.

Litigation

Liabilities for loss contingencies arising from claims, assessments, ligation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

11. Net Loss Per Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net loss per share of common stock				
Numerator:				
Net loss	$ (6,775)	$ (2,832)	$ (13,483)	$ (1,848)
Less cumulative preferred Series D dividends	(194)	(194)	(582)	(582)
Net loss available to common shareholders – basic and diluted	$ (6,969)	$ (3,026)	$ (14,065)	$ (2,430)
Denominator:				
Weighted-average number of shares outstanding used in computing net loss per share, basic and diluted	5,720,009	5,720,009	5,720,009	5,720,009
Net loss per share, basic and diluted	$ (1.22)	$ (0.53)	$ (2.46)	$ (0.42)

The following potentially dilutive securities have been excluded from the calculation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Convertible preferred stock	15,360,787	15,360,787	15,360,787	15,360,787
Stock options to purchase common stock	2,149,138	1,611,041	2,149,138	1,611,041

Amounts in the above table reflect the common stock equivalent.

12. Subsequent Events

In December 2024, the Company received an additional $6.0 million in exchange for a convertible promissory note. The Convertible Note bears an annual interest of 2.0% plus SOFR and shall be due and payable upon the earlier to occur of September 2027 or certain events defined in the Convertible Note. Under certain circumstances, the Convertible Note is convertible at the option of requisite holders into the Company's equity securities at defined conversion prices.

In December 2024, the Company closed the merger receiving $11.4 million of cash from the public company and an additional $66.0 million from the closing of the PIPE, $60.0 million from PIPE investors and $6.0 million received from convertible notes. The total PIPE was $78.4 million in total cash, of which $18.4 million was received under convertible notes, and $60.0 million received at the closing of the PIPE.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Palvella Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Palvella Therapeutics, Inc, (the Company) as of December 31, 2023 and 2022, and the related statements of operations, changes in convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring net losses from operations, incurred negative cash flows from operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Royalty agreement liability and related interest income

Description of the Matter	As described in Note 4 to the financial statements, the Company is party to a development funding agreement with Ligand Pharmaceuticals, Inc. (Ligand) (the Ligand Agreement). Pursuant to the Ligand Agreement, as partial consideration for the upfront payment received from Ligand, the Company agreed to pay to Ligand tiered future royalties based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. The Company recorded its obligation to pay tiered royalties under the Ligand Agreement as a debt instrument (royalty agreement liability) on the balance sheet at a carrying value of $8.1 million as of December 31, 2023 and has recognized imputed interest income of $6.3 million for the year ended December 31, 2023 using the effective interest rate method. The effective interest rate is estimated at each balance sheet date based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. The effective interest rate may vary during the term of the Ligand Agreement based on changes in the probability-adjusted cash flow estimates of the Company's potential future royalty payments under the Ligand Agreement. Auditing the interest income associated with the royalty agreement liability involved complex and subjective auditor judgment due to the estimation uncertainty involved in determining the probability-adjusted cash flow estimates of the Company's potential future royalty payments. The Company's effective interest rate calculation includes probability-adjusted revenue projections for which future royalties will be paid, which are sensitive to significant assumptions including the size of the addressable patient population, the anticipated pricing of the Company's products, and the probability of successful development and commercialization, among others.
How We Addressed the Matter in Our Audit	To test the interest income associated with the royalty agreement liability, our audit procedures included, among others, testing the significant assumptions used to develop the estimates and evaluating the completeness and accuracy of the underlying data used by the Company in its effective interest rate calculation. For example, we compared the estimated size of the addressable patient population to a third-party prevalence study and government census data, and we compared the anticipated pricing information to a third-party market analysis. We compared the probability of achieving development and commercial success to studies published in medical journals evaluating clinical advancement and approval rates for similar products. We tested that the revenue projections were updated based on the most recent clinical trial data received in 2023 and recalculated the current year interest income.

Fair value of royalty agreement liability recorded upon extinguishment

Description of the Matter	As described in Note 3 and 4 to the financial statements, the Ligand Agreement was amended in November 2023 (the Amended Ligand Agreement), resulting in an extinguishment of the royalty agreement liability and recording of a new royalty agreement liability at its estimated fair value of $7.8 million on the date of the amendment. This resulted in a non-cash gain on extinguishment of approximately $23.1 million being recorded in the statement of operations during the year ended December 31, 2023. The Company estimated the fair value of the royalty agreement liability utilizing a Monte Carlo valuation model. Auditing the estimated fair value of the royalty agreement liability was complex and involved a high degree of subjectivity as the fair value is based on various inputs and assumptions, such as the net sales discount rate and the continuous counterparty discount rate.
How We Addressed the Matter in Our Audit	To test the estimated fair value of the royalty agreement liability, our audit procedures included, among others, testing the Monte Carlo valuation model and assessing the reasonableness of the significant assumptions used in the model. We involved valuation specialists to assess the appropriateness of the valuation model and to perform comparative calculations to corroborate the accuracy of the output from the Company's model. With the assistance of our valuation specialists, we compared the key assumptions used in developing the discount rates to available market data and comparable company information.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.
Philadelphia, Pennsylvania
August 9, 2024

PALVELLA THERAPEUTICS, INC.

BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,350	$ 16,053
Prepaid expenses and other current assets	198	471
Total current assets	7,548	16,524
Total assets	$ 7,548	$ 16,524
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 936	$ 3,181
Accrued expenses and other current liabilities	1,424	2,601
Total current liabilities	2,360	5,782
Royalty agreement liability	8,054	32,417
Derivative liabilities – royalty agreement	1,014	1,499
Total liabilities	11,428	39,698
Commitments and contingencies (Note 9)		
Convertible preferred stock, $0.00001 par value; 20,655,895 shares authorized; 15,360,787 shares issued and outstanding at December 31, 2023 and 2022; aggregate liquidation value of $65,377 at December 31, 2023	70,603	70,603
Stockholders' deficit:		
Common stock, $0.00001 par value; 29,000,000 (25,500,000 voting and 3,500,000 non-voting) shares authorized; 5,720,009 (5,050,000 voting and 670,009 non-voting) shares issued and outstanding at December 31, 2023 and 2022	—	—
Additional paid-in capital	1,818	1,215
Accumulated deficit	(76,301)	(94,992)
Total stockholders' deficit	(74,483)	(93,777)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 7,548	$ 16,524

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 8,793	$ 13,884
General and administrative	3,076	4,156
Total operating expenses	11,869	18,040
Operating loss	(11,869)	(18,040)
Other income (expense):		
Interest income (expense) - royalty agreement	6,265	(10,364)
Fair value adjustments on derivative liabilities - royalty agreement	485	(300)
Gain on extinguishment – royalty agreement	23,098	—
Other income, net	712	126
Income (loss) before income taxes	18,691	(28,578)
Income tax benefit	—	1,026
Net income (loss)	$ 18,691	$ (27,552)
Less: Cumulative Series D preferred dividends	(776)	—
Net income (loss) attributable to common stockholders	17,915	(27,552)
Net income (loss) per share of common stock:		
Basic	$ 0.68	$ (4.82)
Diluted	$ 0.67	$ (4.82)
Weighted-average shares used in computing net income (loss) per share of common stock:		
Basic	5,720,009	5,718,926
Diluted	5,796,956	5,718,926

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	13,525,560	$ 61,071	5,708,030	$ —	$ 754	$ (67,440)	$ (66,686)
Issuance of Series D preferred stock, net of issuance costs of $173	1,835,227	9,532	—	—	—	—	—
Stock options exercised	—	—	11,979	—	34	—	34
Stock-based compensation	—	—	—	—	427	—	427
Net loss	—	—	—	—	—	(27,552)	(27,552)
Balance at December 31, 2022	15,360,787	$ 70,603	5,720,009	$ —	$ 1,215	$ (94,992)	$ (93,777)
Stock-based compensation	—	—	—	—	603	—	603
Net income	—	—	—	—	—	18,691	18,691
Balance at December 31, 2023	15,360,787	$ 70,603	5,720,009	$ —	$ 1,818	$ (76,301)	$ (74,483)

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities		
Net income (loss)	$ 18,691	$ (27,552)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest (income) expense – royalty agreement	(6,265)	10,364
Change in fair value of derivative liabilities – royalty agreement	(485)	300
Gain on extinguishment – royalty agreement	(23,098)	—
Stock-based compensation	603	427
Change in operating assets and liabilities:		
Prepaid expenses and other assets	273	695
Accounts payable	(2,245)	1,980
Accrued expenses and other current liabilities	(1,177)	(1,054)
Net cash used in operating activities	(13,703)	(14,840)
Cash flows from financing activities		
Proceeds from issuance of Series D preferred stock, net	—	9,532
Proceeds from amendment to royalty agreement	5,000	—
Exercise of stock options	—	34
Net cash provided by financing activities	5,000	9,566
Net decrease in cash and cash equivalents	(8,703)	(5,274)
Cash and cash equivalents at beginning of year	16,053	21,327
Cash and cash equivalents at end of year	$ 7,350	$ 16,053

The accompanying notes are an integral part of these financial statements

PALVELLA THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Description of Business, Organization and Liquidity

Business

Palvella Therapeutics, Inc. (the "Company") is a late clinical-stage biopharmaceutical company committed to serving individuals suffering from serious, rare genetic skin diseases without approved therapies. The Company's lead product candidate, QTORIN 3.9% rapamycin anhydrous gel ("QTORIN rapamycin"), is based on the Company's patented QTORIN platform. QTORIN rapamycin is in clinical development for two rare genetic skin disorders. Since inception, the Company has devoted substantially all of its time to identifying, researching and conducting preclinical and clinical activities for its product candidates, acquiring and developing its platform technology, organizing and staffing the Company, business planning, raising capital and establishing its intellectual property portfolio. The Company's principal executive offices are located in Wayne, Pennsylvania.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2023, the Company reported net income of $18.7 million due primarily to a $23.1 million non-cash gain on extinguishment of the royalty agreement (see Note 4) but has incurred net losses in all previous years. During the year ended December 31, 2023, the Company had net cash used in operating activities of $13.7 million and had an accumulated deficit of $76.3 million as of December 31, 2023.

The Company has financed its operations to date primarily through the sale of its convertible preferred stock, funding received under a royalty agreement, and entering into a convertible note purchase agreement under which the Company raised $11.9 million of gross proceeds from the issuance of convertible promissory notes through the issuance date of these financial statements that are convertible into the Company's common stock based on certain conditions and events. Management does not expect to generate commercial revenue or operating cash flows for at least the next several years. The Company's ability to continue as a going concern in the near term is largely dependent on its ability to obtain additional sources of financing in order to fund operating expenses, complete development of its product candidates, obtain regulatory approvals, launch, and commercialize its product candidates, and continue research and development programs. The Company's forecasted cash required to fund operations indicates that the Company does not have sufficient funds to support operations through the one-year period from the issuance date of these financial statements. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

Management's plans to address this going concern uncertainty include raising additional financing through public or private equity offerings, debt financings, collaborations and licensing arrangements, strategic transactions, or other sources to fund its operations; however, there can be no assurance that the Company will be able to obtain such funding on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on the Company's business, results of operations and financial condition.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts of classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any references in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process and actual results could differ materially from those estimates.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company holds all cash at two accredited financial institutions in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company is dependent on contract manufacturing organizations ("CMOs") to supply products for research and development of its product candidates, including pre-clinical and clinical studies, and for commercialization of its product candidates, if approved. The Company's development programs could be adversely affected by any significant interruption in its CMOs' operations or by a significant interruption in the supply of active pharmaceutical ingredients and other components.

Products developed by the Company require approval from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's product candidates will receive the necessary approvals. If the Company is denied approvals, approvals are delayed, or it is unable to maintain approvals received, such events could have a materially adverse impact on the Company.

Cash and cash equivalents

Cash and cash equivalents are held in accounts at two independent financial institutions. Cash equivalents are defined as all highly liquid investments with maturity from date of purchase of 90 days or less that are readily convertible into cash. Cash equivalents include money market funds that invest primarily in U.S. Treasury securities.

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

At December 31, 2023 and 2022, the carrying amounts of financial instruments, which include cash and cash equivalents, accounts payable, and accrued expenses and other liabilities, approximate their fair value due to their short maturities. The Company records its derivative liabilities at fair value. At December 31, 2023, the fair value of the royalty agreement liability approximates its carrying value since the royalty agreement liability was remeasured at fair value in connection with the November 2023 amendment to its development funding and royalties agreement with Ligand Pharmaceuticals, Inc. ("Ligand") (the "Ligand Agreement") (see Note 4).

Derivative instruments

The Company has milestone payments which may be required in connection with the royalty agreement (see Note 4) that were determined to be derivative liabilities. The valuation of the derivative liabilities is based on unobservable inputs and, therefore, represent Level 3 financial liabilities. The fair value of the derivative liabilities – royalty agreement was calculated using the present value of the potential payments using a weighted-average cost of capital and an assessment of the probability of the achievement of the milestones as well as an assessment of the timing of the potential milestone payments.

The derivative liabilities – royalty agreement was initially recorded at fair value, with gains and losses arising for changes in fair value of the derivative liabilities – royalty agreement recognized within the statements of operations as fair value adjustments on the derivative liabilities at each financial reporting period.

Research and development expenses

Research and development costs are charged to expense as incurred. Research and development expenses include, among other costs, salaries and benefits of scientific personnel and the external cost of producing and testing the clinical material for clinical trials.

The Company has entered various research and development and clinical trial-related contracts. The Company defers and capitalizes prepaid nonrefundable advance research and development payments to third parties for goods and services to be used in future research and development activities and recognizes to research and development expense over the period that the research and development activities are performed or the services are provided. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and clinical trial costs. When determining the accruals, at the end of a reporting period, the Company analyzes progress of its studies and clinical trials, including the phase or completion of events, invoices received and contracted costs. Actual results could differ from the Company's estimates.

Stock-based compensation

The Company measures all stock options and other stock-based awards granted to employees, directors, consultants, and other nonemployees based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period on a straight-line basis, which is generally the vesting period of the respective award. The Company recognizes forfeitures at the time forfeitures occur.

The Company classifies stock-based compensation expense in its statements of operations in the same way the payroll costs or service payments are classified for the related stock-based award recipient.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model ("Black-Scholes"). Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method to calculate the expected term for options granted whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

As the Company's common stock has not been publicly traded, the Company periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants ("AICPA"), *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The Company's stock valuations were prepared using either a hybrid method, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or a probability-weighted expected return method, or PWERM, where the fair value of common stock is estimated based upon an analysis of future values for the Company, assuming various outcomes. Under the PWERM, the common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. In addition to considering the results of these third-party valuations, the Company considered various objective and subjective factors to determine the price of its common stock as of each grant date, which may be as of a date later than the most recent third-party valuation date.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all the tax benefits will not be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrued liability for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. The Company has elected to treat interest and penalties, to the extent they arise, as a component of income taxes.

Related party transactions

The Company's board of directors reviews and approves transactions with directors, officers, and holders of 5% or more of its voting securities and their affiliates, each a related party. The material facts as to the related party's relationship or interest in the transaction are disclosed to its board of directors prior to their consideration of such transaction, and the transaction is not considered approved by its board of directors unless a majority of the directors who are not interested in the transaction approve the transaction.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

Net income (loss) per share

The Company's convertible preferred stock are participating securities. Accordingly, in any period in which the Company reports net income attributable to common stockholders, basic earnings per share is computed using the "two-class" method. Under this method, net income is reduced by any dividends earned and the remaining earnings (undistributed earnings) are allocated to common stock and each series of convertible preferred stock to the extent that each preferred security may share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses. Diluted net income (loss) per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus, for periods with net income attributable to common shareholders, the potential dilutive effects of outstanding stock options. In addition, the Company analyzes the potential dilutive effect of the outstanding convertible preferred stock under the "if-converted" method when calculating diluted earnings per share, in which it is assumes that the outstanding convertible preferred stock converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (two class or "if-converted") as their diluted net income per share during the period. For years in which a net loss exists, the weighted-average number of shares of common stock is the same for basic and diluted net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. See Note 10 for further details on the Company's net income (loss) per share calculations.

Recently adopted accounting standards

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326) ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial instruments based on historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 was adopted by the Company on January 1, 2023 and it did not have a material effect on its financial statements or related disclosures.

Recently issued accounting standards

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 for public companies and December 15, 2025 for private companies and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of the ASU on the income tax disclosures within its financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures which requires that a public entity provide additional segment disclosures on an interim and annual basis. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements, unless impracticable. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. For public companies the ASU is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. For private companies the ASU is effective for fiscal years starting after December 15, 2024, and interim periods within those fiscal periods. Early adoption is permitted. The Company is currently evaluating the impact of the adoption on the Company's segment disclosures within its financial statements.

3. Fair Value Measurements

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Current assets:				
Money market funds	$ 7,203	$ —	$ —	$ 7,203
Total assets measured at fair value	$ 7,203	$ —	$ —	$ 7,203
Liabilities:				
Derivative liabilities – royalty agreement	$ —	$ —	$ 1,014	$ 1,014
Total liabilities measured at fair value	$ —	$ —	$ 1,014	$ 1,014

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Current assets:				
Money market funds	$ 15,203	$ —	$ —	$ 15,203
Total assets measured at fair value	$ 15,203	$ —	$ —	$ 15,203
Liabilities:				
Derivative liabilities – royalty agreement	$ —	$ —	$ 1,499	$ 1,499
Total liabilities measured at fair value	$ —	$ —	$ 1,499	$ 1,499

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds is based on quoted prices in active markets for identical securities. This approach results in a classification of these securities as Level 1 of the fair value hierarchy. Money market funds are cash equivalents and are included in cash and cash equivalents on the Company's balance sheet as of December 31, 2023 and 2022.

The key assumptions used to determine the fair value of the derivative liabilities – royalty agreement at December 31, 2023 and 2022 are as follows:

	December 31,	
	2023	2022
Discount rate	25.0%	25.0%
Probability rate of achieving FDA approval of a product	50%	50%
Expected term to FDA regulatory approval of a product (in years)	3.50	1.75

The following table provides a reconciliation of the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	2023	2022
Derivative liabilities – royalty agreement		
Balance at January 1	$ 1,499	$ 1,199
Fair value adjustments on derivative liabilities	(485)	300
Balance at December 31	$ 1,014	$ 1,499

The derivative liabilities – royalty agreement is classified as long term on the Company's balance sheets according to the estimated timing of the occurrence of the potential payments.

As discussed in Note 4 below, the Amended Ligand Agreement was initially measured at its estimated fair value. This nonrecurring fair value measurement was based upon Level 3 inputs. The Company estimated the fair value of the royalty agreement liability on the amendment date using a Monte Carlo valuation model. The Company derived risk-adjusted quarterly net sales forecasts by applying a net sales discount rate of 21% to its forecasted net sales over the royalty term, and then simulated the risk-adjusted net sales using a Monte Carlo simulation. Based on the simulated net sales, the Company estimated the royalty payments within each simulation path based on the contractual royalty rates, and then present valued the royalty payments using a discount rate of 22%, which was based on its estimated discrete weighted average cost of capital of 24.5% as of the amendment date, adjusted to reflect the continuously compounded nature of the analysis. The Company then averaged across all simulation paths to derive the fair value of the royalty agreement liability on the date of amendment of $7.8 million.

4. Strategic Agreements

Ligand Development Funding Agreement

In December 2018, the Company entered into the Ligand Agreement with Ligand, whereby Ligand agreed to make a one-time payment of $10.0 million to fund the development of QTORIN rapamycin. As partial consideration for the one-time payment, the Company granted Ligand the right to receive up to $8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by the Company related to QTORIN rapamycin for the treatment of any and all indications. In addition, the Company agreed to pay to Ligand tiered royalties from 5.0% to 9.8% based on any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. On a licensed product-by-licensed product and country-by-country basis, the royalty period is from the date of first commercial sale of such licensed product in a country until the latest of (i) the expiration of the last valid claim within the licensed patent rights covering such licensed product in the country in which such licensed product is made, used or sold, (ii) the expiration of the regulatory exclusivity term conferred by the applicable regulatory authority in such country with respect to such licensed product, and (iii) the fifteenth anniversary of the first commercial sale of such licensed product in such country. In certain circumstances, the Company has the right to reduce the royalty rates under the Ligand Agreement by making payments ("Royalty Buy Down Payments"). Specifically, once the Company has made royalty payments to Ligand equal to certain specified amounts in the mid eight figures, the Company has the option to make Royalty Buy Down Payments at any time during the remainder of the term of the Ligand Agreement to reduce its certain royalty tier percentages on annual worldwide net sales of any products by one or two percentage points. Such Royalty Buy Down Payments range in size from the low seven figures to the low eight figures.

Ligand may terminate the agreement for any or no reason upon a 90-day notice to the Company. Ligand may also terminate the agreement for cause in connection with a material breach that the Company does not cure within a certain period of time.

The total amount of potential future milestone payments remaining under the arrangement were $5.0 million as of December 31, 2023 and 2022. The potential future milestone payments represent derivative liabilities with a fair value of $1.0 million and $1.5 million as of December 31, 2023 and 2022, respectively, which are classified as derivative liabilities – royalty agreement on the accompanying balance sheets. See Note 3 for fair value measurements.

The Company's obligation to pay tiered royalties under the Ligand Agreement was determined to be a debt instrument based on the likelihood of repaying the amounts provided to fund the development of QTORIN rapamycin and that the Company has significant continuing involvement in the generation of the cash flows potentially due to Ligand. This obligation is reflected as royalty agreement liability which is classified as a long-term liability on the accompanying balance sheets. Interest expense with respect to the royalty agreement liability is determined using the effective interest method based upon probability-adjusted cash flow estimates of the Company's potential future royalty payments under the Ligand Agreement, yielding an effective interest rate of 38.9% and 30.3% as of December 31, 2023 and 2022, respectively. The effective interest rate is estimated at each balance sheet date based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. Changes in these estimates impact the amount of interest expense recognized through the accompanying statements of operations. During the second quarter of 2023, the Company received data from certain of its clinical trials that reduced the projected net product sales related to QTORIN rapamycin and the corresponding probabilities of successful commercialization, resulting in a significant reduction in the expected future royalty payments and a corresponding reduction in the royalty agreement liability as of December 31, 2023. The Company incurred non-cash interest income (expense) of $6.3 million and ($10.4) million for the years ended December 31, 2023 and 2022, respectively, all of which is a component of the royalty agreement liability on the accompanying balance sheets.

In November 2023, the Ligand Agreement was amended (the "Amended Ligand Agreement"), whereby Ligand paid the Company an additional $5.0 million in return for an increase in the future tiered royalties to 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin The Royalty Buy Down Payments, and the associated rate modifications, in the original agreement were eliminated as part of the amendment. The Amended Ligand Agreement also replaced the termination provision so that the agreement may be terminated by the earlier of a mutual written agreement of the parties or when the royalties contemplated by the agreement are paid to Ligand. The Company evaluated the accounting for the Amended Ligand Agreement under ASC 470, *Debt*, and concluded that the present value of the cash flows under the Amended Ligand Agreement differed by more than 10% from the present value of the cash flows under the original Ligand Agreement. As such, the Ligand Agreement was extinguished and the Amended Ligand Agreement was recorded at the estimated fair value of the royalty agreement liability on the date of the amendment. This resulted in a non-cash gain on extinguishment of approximately $23.1 million being recorded in the accompanying statement of operations related to the difference between the carrying value of the liability and its estimated fair value of $7.8 million on the date of amendment. See Note 3 for fair value measurements.

The Amended Ligand Agreement includes an option for Ligand to purchase additional product revenue participation rights from Palvella over a 10-year period. The option allows Ligand, for each product developed on the QTORIN platform that completes the first human clinical trial in the United States, the opportunity to make an upfront payment to Palvella (as set forth in the Amended Ligand Agreement) in return for a royalty rate (as set forth in the Amended Ligand Agreement). The Company determined that the option to purchase additional product revenue participation rights was not a freestanding financial instrument as it was not separately exercisable and legally detachable. The Company also determined that the option did not meet the definition of a derivative subject to bifurcation as it does not have a net settlement characteristic.

The Ligand Agreement requires the Company to make certain estimates and assumptions about the timing and probability of FDA approval and commercialization, and the amount of future net sales for any product containing QTORIN rapamycin. The estimated future net sales are based on subjective assumptions that include the estimated size of the addressable patient population and the anticipated pricing of the Company's products. These estimates and assumptions are subject to significant variability and are thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as the Company develops and commercializes products containing QTORIN rapamycin that may result in significant future adjustments to the royalty agreement liability, the derivative liabilities, and the accretion of interest expense.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2023	**2022**
Professional fees	$ 960	$ 997
Compensation expense	175	762
Research and development expenses	120	683
Other	169	159
Total accrued expenses and other current liabilities	$ 1,424	$ 2,601

6. Convertible Preferred Stock

In December 2022, the Company issued 1,835,227 shares of Series D Convertible Preferred Stock ("Series D Preferred") at a price of $5.29 per share. The Series D Preferred also contains a Milestone Closing option for additional shares to be issued following the Company's receipt of clinical data for the top line Phase 3 data results for QTORIN rapamycin for pachyonychia congenita. Under the Milestone Closing, each Purchaser of the Series D Preferred shall have the right to purchase, and the Company agrees to sell and issue to each Purchaser at the Milestone Closing, up to that portion of 4,727,775 shares of Series D Preferred which equals the proportion that the number of shares of Series D Preferred then held by such Purchaser bears to the total number of shares of Series D Preferred outstanding immediately prior to the Milestone Closing, at a purchase price of $5.29 per share. The Company determined that the future tranche right to purchase additional shares of Series D Preferred was not a freestanding financial instrument as it was not separately exercisable and legally detachable. The future tranche right was evaluated as an embedded derivative and was not bifurcated from the Series D Preferred shares since it did not have a net settlement characteristic and therefore did not meet the definition of a derivative. The future tranche right was cancelled in July 2024.

In connection with the issuance of the Series D Preferred, the Company amended and restated its certificate of incorporation (as amended, the "Amended Certificate") such that it is authorized to issue 29,000,000 shares of common stock (25,500,000 voting and 3,500,000 non-voting) and 20,655,895 shares of preferred stock, with 2,241,903 shares designated as Series A-1 Convertible Preferred stock (Series A-1 Preferred"), 1,240,134 shares designated as Series A-2 Convertible Preferred stock ("Series A-2 Preferred"), 1,533,528 shares designated as Series B Convertible Preferred stock ("Series B Preferred"), 8,509,995 shares designated as Series C Convertible Preferred stock ("Series C Preferred") and 7,130,335 shares designated as Series D Preferred.

The following tables summarize outstanding convertible preferred stock (in thousands, except share and per share amounts):

	December 31, 2023 and 2022			December 31, 2023
	Original Issue Price Per Share	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference
Series A-1 Preferred	$ 1.31	2,241,903	2,241,903	$ 2,937
Series A-2 Preferred	$ 1.64	1,240,134	1,240,134	2,034
Series B Preferred	$ 3.19	1,533,528	1,533,528	4,892
Series C Preferred	$ 5.29	8,509,995	8,509,995	45,000
Series D Preferred	$ 5.29	7,130,335	1,835,227	10,514
		20,655,895	15,360,787	$ 65,377

The rights and preferences of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred, Series C Preferred and Series D Preferred, collectively Preferred Stock, under the Amended Certificate are as follows:

Dividends

The Series D Preferred holders, in preference to holders of any other series of the Company's stock, are entitled to cumulative dividends in an amount in cash equal to 8% of the applicable Series D Preferred original issue price of $5.29 per annum on each outstanding share of such Series D Preferred calculated from the date of issuance of such share, if and when declared by the Company's board of directors. The Series C Preferred holders, in preference to holders of any other series of the Company's stock other than the Series D Preferred, are entitled to non-cumulative dividends in an amount in cash equal to 8% of the applicable Series C Preferred original issue price of $5.29 per annum on each outstanding share of such Series C Preferred calculated from the date of issuance of such share, if and when declared by the Company's board of directors. The holders of Preferred Stock and Common Stock are entitled to participate in the distribution of the dividend as they would have received if all outstanding shares of Preferred Stock had been converted into common stock on the date of such event, after all holders of the Series D Preferred and the Series C Preferred have received such dividend in full. No dividends were declared or paid as of December 31, 2023. The Series D Preferred cumulative preferred stock dividends in arrears were approximately $0.8 million as of December 31, 2023 and were de minimis as of December 31, 2022.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of the Series D Preferred shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of Series D Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred, Series C Preferred and Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price plus and accrued but unpaid cumulative dividends, or (ii) such amount per share as would have been payable had all shares of Series D Preferred been converted into Common Stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event ("Series D Liquidation Amount").

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of the Series C Preferred shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of Series C Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of the Series A-1 Preferred, Series A-2 Preferred, Series B Preferred and Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price, or (ii) such amount per share as would have been payable had all shares of Series C Preferred been converted into Common Stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event ("Series C Liquidation Amount").

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, after payment in full of the Series D Liquidation Amount to the holders of Series D Preferred and the Series C Liquidation Amount to the holders of the Series C Preferred, holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a deemed liquidation event, as defined in the Amended Certificate, the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such deemed liquidation event or out of the available proceeds, as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price, or (ii) such amount per share as would have been payable had all shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, been converted into common stock immediately prior to such liquidation, dissolution, winding up, or deemed liquidation event. If upon any such liquidation, dissolution, or winding up of the Company or deemed liquidation event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred, the full amount to which they shall be entitled to the holders of shares of Series A-1 Preferred, Series A-2 Preferred, and Series B Preferred shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Voting

The holders of outstanding shares of Preferred Stock are entitled to vote on all matters and shall be entitled to vote based on the number of shares of common stock into which each share of the preferred stock is convertible.

Redemption

Preferred Stock is not subject to mandatory redemption. The Preferred Stock is subject to redemption under certain deemed liquidation events not solely within the control of the Company, as defined, and as such are considered contingently redeemable for accounting purposes and are classified as temporary equity in the Company's balance sheets. The Preferred Stock is not considered probable to become redeemable as no deemed liquidation events are expected to occur.

Conversion

Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (a) the applicable original issue price by (b) the applicable conversion price in effect at the time of conversion.

Preferred Stock automatically converts upon the closing of a firm commitment underwritten initial public offering of common stock, in which the price per share is at least two times the Series D original issue price, subject to adjustment, resulting in gross proceeds of at least $50.0 million to the Company.

Preferred Stock		Preferred Conversion Price to Common Stock
Series A-1 Preferred	$	1.31
Series A-2 Preferred	$	1.64
Series B Preferred	$	3.19
Series C Preferred	$	5.29
Series D Preferred	$	5.29

For Preferred Stock, the preferred conversion price and the rate at which applicable shares may be converted is subject to adjustment upon the occurrence of certain events. As of December 31, 2023 and 2022, the effective conversion ratio for all Preferred Stock is one for one.

7. 2019 Equity Incentive Plan

In March 2019, the Company adopted the 2019 Equity Incentive Plan (the "Plan"), which provides employees, consultants and advisors, and non-employee members of the Board of Directors and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options, and stock awards. In May 2020, the Company amended the 2019 Plan to include an additional 1,000,000 shares available for awards under the Plan. A total of 1,690,000 shares of the Company's non-voting common stock may be issued for the grants under the Plan. As of December 31, 2023, there were 30,000 shares available for future grants under the Plan.

For incentive stock options and non-statutory stock options, the option exercise price may not be less than 100% of the estimated fair value on the date of grant. Options granted to employees typically vest over a four-year period but may be granted with different vesting terms. The options expire ten years from the grant date.

A summary of activity under the Plan for the year ended December 31, 2023 as follows:

	Common Shares Underlying Stock Options		Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding at January 1, 2023	1,024,628	$	2.53	7.1
Granted	608,388		3.03	
Exercised	—			
Forfeited / Cancelled	(51,975)		2.64	
Outstanding at December 31, 2023	1,581,041	$	2.72	7.3
Exercisable at December 31, 2023	1,009,011	$	2.56	6.5

The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2023 was $494,000 and $470,000, respectively.

During the year ended December 31, 2023 and 2022, the Company recognized $603,000 and $427,000, respectively, of stock-based compensation expense, of which $55,000 and $80,000, respectively, was recorded as general and administrative expense and $548,000 and $347,000, respectively, was recorded as research and development expense in the accompanying statements of operations. As of December 31, 2023, there was approximately $1.2 million of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average service period of 2.7 years.

The weighted average fair value of stock options granted during the year ended December 31, 2023 was $2.16 per share which was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Expected volatility	80.14% - 81.01%
Risk-free interest	4.05% - 4.08%
Expected term (years)	5.4 - 6.0
Expected dividend yield	—

There were no stock options granted during the year ended December 31, 2022.

8. Income Taxes

The Company had no provision for income taxes for the year ended December 31, 2023. The Company recorded a benefit for income taxes of $1.0 million for the year ended December 31, 2022 which consisted of approximately $0.1 million of current federal tax benefit and $0.9 million of current state tax benefit. The 2022 tax benefit is attributed to the reversal of the Company's uncertain tax position due to the lapse of the 2018 Pennsylvania statute of limitations concerning the timing of the initial upfront payment received under the Ligand Agreement.

A reconciliation of the statutory U.S. federal income tax rate to the Company’s effective tax rate is as follows:

	December 31,	
	2023	2022
U.S. federal statutory rate	21.0%	21.0%
Uncertain tax position and interest	0.0	3.8
State and local taxes	4.0	(3.9)
Permanent items	0.3	(1.0)
Change in valuation allowance	(25.4)	(16.3)
Other	0.1	0.0
Effective income tax rate	0.0%	3.6%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Royalty agreement liabilities	$ 1,587	$ 9,080
Net operating loss	9,179	7,850
Section 174 R&D capitalization	4,548	3,152
Accrued expenses and other	406	364
Orphan drug credit	199	199
Startup costs	95	104
Net deferred tax assets	16,014	20,749
Valuation allowance	(16,014)	(20,749)
Net deferred tax assets	$ —	$ —
Decrease (increase) in valuation allowance	$ 4,735	$ (4,637)

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOLs. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized. As such, there is a full valuation allowance in the amount of $16.0 million and $20.7 million against the net deferred tax assets as of December 31, 2023 and 2022, respectively.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2023, the Company reported no liabilities for unrecognized tax benefits along with no related interest and penalty exposure as accrued income tax on the accompanying balance sheets. Income tax returns for the tax years 2019 through 2023 remain subject to examination by the taxing authority jurisdictions.

At December 31, 2023, the Company had NOLs for federal income tax purposes of $36.7 million, which are available to reduce future federal taxable income and have an indefinite carryforward. The Company has NOLs for state income tax purposes of $37.6 million, which are available to reduce future state taxable income through 2038. In addition, the Company has orphan drug credits of $0.2 million to reduce future federal taxes through 2039.

9. Commitments and Contingencies

Lease

The Company leases office space in Wayne, Pennsylvania, under a lease agreement, as amended, expiring on October 31, 2024 that had an initial term of less than 12 months. The minimum lease payments due under this lease are as follows as of December 31, 2023 (in thousands):

Year ended December 31,	
2024	$ 67
Total future minimum payments	$ 67

Rent expense recorded during the years ended December 31, 2023 and 2022 was $80,000.

Litigation

Liabilities for loss contingencies arising from claims, assessments, ligation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

10. Net Income (Loss) Per Share

Basic and diluted net income (loss) per share is calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	**2022**
Net income (loss) per share of common stock		
Numerator:		
Net income (loss) attributable to common stockholders	$ 17,915	$ (27,552)
Less: non-cumulative preferred Series C dividends	(3,600)	—
Less: allocation of undistributed earnings to participating securities - preferred stock	(10,431)	—
Net income (loss) attributable to common stockholders – basic and diluted	$ 3,884	$ (27,552)
Denominator:		
Weighted-average number of shares outstanding used in computing net income (loss) per share - basic	5,720,009	5,718,926
Effect of dilutive securities:		
Stock options	76,947	—
Denominator for diluted net income (loss) per share – adjusted weighted average shares	5,796,956	5,718,926
Net income (loss) per share, basic	$ 0.68	$ (4.82)
Net income (loss) per share, diluted	$ 0.67	$ (4.82)

The following potentially dilutive securities have been excluded from the calculation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	December 31,	
	2023	**2022**
Convertible preferred stock	15,360,787	15,360,787
Stock options to purchase common stock	1,119,732	1,024,628

Amounts in the above table reflect the common stock equivalent.

11. Subsequent Events

On July 23, 2024, Pieris Pharmaceuticals, Inc., a Nevada corporation ("Pieris") that is listed on the Nasdaq exchange, Polo Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Pieris ("Merger Sub"), and the Company, entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which the Merger Sub will merge with and into the Company, with the Company continuing as a wholly-owned subsidiary of Pieris and the surviving corporation of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization and as a non-taxable exchange of shares of the Company's capital stock for Pieris common stock.

Subject to the terms and conditions of the Merger Agreement (a) each then-outstanding share of the Company's capital stock will be converted into the right to receive a number of shares of Pieris common stock (subject to the payment of cash in lieu of fractional shares) calculated in accordance with the Merger Agreement; and (b) each then-outstanding stock option to purchase the Company's common stock will be assumed by Pieris, subject to adjustment as set forth in the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by Pieris stockholders, (2) approval by the Company's stockholders, and (3) Nasdaq's approval of the listing of the shares of Pieris common stock to be issued in connection with the Merger.

The Merger Agreement contains certain termination rights of each of Pieris and the Company, including the right of each party to terminate the Merger Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Merger Agreement under specified circumstances, Pieris may be required to pay the Company a termination fee of $1.0 million and the Company may be required to pay Pieris a termination fee of $2.0 million.

In June 2024, the Company entered into a Convertible Note Purchase Agreement (the "Convertible Note") with certain existing and new investors for the issuance of up to $20 million of convertible promissory notes. Through the issuance date of these financial statements, the Company has received $11.9 million of gross proceeds in exchange for convertible promissory notes issued. The Convertible Note bears an annual interest of 2.0% plus SOFR and shall be due and payable upon the earlier to occur of June 2027 or certain events defined in the Convertible Note. Under certain circumstances, the Convertible Note is convertible at the option of requisite holders into the Company's equity securities at defined conversion prices. The terms of the Convertible Note specify that upon the consummation of the Merger, all outstanding principal and any unpaid accrued interest on the notes shall be automatically converted into common stock of Palvella.

In March 2024, the Company amended the 2019 Plan to include an additional 1,171,768 shares available for awards under the Plan.

Subsequent events have been evaluated through August 9, 2024, which is the date the accompanying financial statements were issued.

Palvella Therapeutics, Inc.

Up to 5,634,504 Shares of Common Stock

PROSPECTUS

January 16, 2025