Palvella Therapeutics and Pieris Pharmaceuticals Announce Definitive Merger Agreement

Wednesday, 24 July 2024 06:30 AM

Proposed merger to create a Nasdaq-listed, clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for serious, rare genetic skin diseases for which there are no FDA-approved therapies

Combined company is expected to have approximately $80.5 million of cash and cash equivalents at closing, including approximately $78.9 million from an oversubscribed private financing with participation from a syndicate of leading healthcare-dedicated investors, which is expected to provide cash runway into the second half of 2027

Anticipated cash and cash equivalents are expected to fund combined company through multiple clinical trial milestones, including pivotal Phase 3 clinical trial results from a single-arm, baseline-controlled clinical trial of QTORIN™3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations currently being conducted under FDA's Breakthrough Therapy Designation and Fast Track Designation programs

QTORIN™ rapamycin has the potential to be the first approved therapy and standard of care in the U.S. for microcystic lymphatic malformations and cutaneous venous malformations, if approved

Companies to host joint webcast on Wednesday, July 24 at 8:30am ET

WAYNE, PA AND BOSTON, MA / ACCESSWIRE / July 24, 2024 / Palvella Therapeutics, Inc. (Palvella), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, and Pieris Pharmaceuticals, Inc. (Nasdaq: PIRS) (Pieris) today announced they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The combined company will focus on developing and

commercializing Palvella's lead clinical product candidate, QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), for the treatment of microcystic lymphatic malformations (microcystic LMs), cutaneous venous malformations, and other serious, functionally debilitating skin diseases driven by the overactivation of the mammalian target of rapamycin (mTOR) pathway. Upon completion of the proposed merger, the combined company will operate under the name Palvella Therapeutics, Inc., will be headquartered in Wayne, PA, and is expected to trade on The Nasdaq Capital Market (Nasdaq).

In connection with the proposed merger, Palvella has secured commitments from a syndicate of leading healthcare-dedicated investors in an oversubscribed $78.9 million concurrent private financing co-led by BVF Partners, L.P., an existing investor, and Frazier Life Sciences, a new investor. Additional new investors include Blue Owl Healthcare Opportunities, Nantahala Capital, DAFNA Capital Management, ADAR1 Capital Management, and a healthcare dedicated fund. Existing investors Samsara BioCapital, Petrichor, CAM Capital, Ligand Pharmaceuticals (Nasdaq: LGND), Integrated Finance Group (an AscellaHealth partner company), BioAdvance, and Gore Range Capital also committed to participate in the financing. The concurrent private financing includes approximately $18.9 million in principal and interest from Palvella convertible notes that will be funded prior to the close and convert into shares of common stock of the combined company. The concurrent private financing is expected to close immediately following the completion of the proposed merger.

The combined company is expected to have approximately $80.5 million of cash and cash equivalents at closing of the proposed merger and concurrent private financing, inclusive of the net proceeds expected to be received in the concurrent private financing and after deducting operating expenses incurred prior to closing and estimated transaction expenses. These cash resources are expected to be used to advance Palvella's product candidate QTORIN™ rapamycin through multiple clinical data milestones and are expected to fund the combined company's operations into the second half of 2027. The proposed merger and concurrent private financing are expected to close in the fourth quarter of 2024, subject to stockholder approval of both companies, the effectiveness of a registration statement to be filed with the U.S. Securities and Exchange Commission (SEC) to register the shares of Pieris common stock to be issued in connection with the merger, and the satisfaction of customary closing conditions. Pieris pre-merger stockholders will also be issued a contingent value right (CVR) representing the right to receive payments from proceeds received by the combined company, if any, under Pieris' existing partnership agreements with Pfizer and Boston Pharmaceuticals.

"We are pleased to announce our merger with Pieris, allowing Palvella to become a publicly traded company and pursue our vision of becoming the leading rare disease company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases," said Wes Kaupinen, Founder and Chief Executive Officer (CEO) of Palvella. "The expected proceeds from the merger and concurrent private financing are expected to fund us through multiple clinical trial milestones, including generating results from the single-arm, baseline-controlled Phase 3 clinical trial of QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations, a serious, rare and chronically debilitating genetic disease for which there are currently no FDA-approved therapies."

"This transaction represents Pieris' deep commitment to delivering value to its stockholders by preserving the future potential milestone and royalty streams from our partnered immuno-oncology bispecifics franchise for Pieris legacy stockholders through the CVRs, while also providing the opportunity for upside in an attractive, late-stage, rare disease company," said Stephen S. Yoder, President and CEO of Pieris. "With the anticipated funding and an accomplished management team, we believe Palvella is well-positioned to advance a Phase 3 clinical program with the FDA's Breakthrough, Fast Track, and Orphan Drug Therapy Designations. This transaction is the culmination of a comprehensive review of strategic alternatives, and our board of directors believes that the merger with Palvella is in the best interests of our stockholders."

Palvella's QTORIN™ Platform and QTORIN™ rapamycin

Palvella's research team developed QTORIN, a patented and versatile platform designed to generate novel topical therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of serious, rare genetic skin diseases.

QTORIN™ rapamycin is the lead product candidate from Palvella's QTORIN platform. QTORIN™ rapamycin is a novel, patented 3.9% rapamycin anhydrous gel, which aims to harness the potential therapeutic benefits of rapamycin, an mTOR inhibitor, while minimizing systemic exposure of rapamycin and potential adverse reactions associated with systemic therapy. QTORIN rapamycin is currently under development for the treatment of microcystic LMs, cutaneous venous malformations, and other serious, functionally debilitating skin diseases driven by the overactivation of the mammalian target of rapamycin (mTOR) pathway. QTORIN™ rapamycin is protected by multiple issued composition patents in the U.S. and Japan and pending patent applications broadly covering anhydrous gel formulations of rapamycin in the U.S., Europe, and Japan.

QTORIN™ Rapamycin for the Treatment of Microcystic LMs

Palvella initiated research on QTORIN™ rapamycin as a targeted therapy for microcystic LMs in 2017 based on scientific insights implicating abnormal activation of the mTOR pathway in this disease. Microcystic LMs is a rare, chronically debilitating genetic disease caused by dysregulation of the phosphatidylinositol 3-kinase (PI3K)/mTOR pathway. The disease is characterized by malformed lymphatic vessels that protrude through the skin and persistently leak lymph fluid (lymphorrhea) and bleed, often leading to recurrent serious infections and cellulitis. The natural history of microcystic LMs is progressive, with symptoms generally worsening during life, including increases in the number and size of malformed vessels that lead to complications and lifetime morbidity. There are currently no FDA-approved treatments for the estimated more than 30,000 diagnosed patients with microcystic LMs in the United States.

In November 2023, based on Phase 2 clinical trial results, Palvella received FDA Breakthrough Therapy Designation for QTORIN™ rapamycin for microcystic LMs. Palvella previously announced positive 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. In addition to Breakthrough Therapy Designation, the FDA has granted both Fast Track Designation and Orphan Drug Designation to QTORIN™ rapamycin for the treatment of microcystic LMs.

In February 2023, Palvella had an End of Phase 2 meeting and, in April 2024, a Type B Breakthrough Therapy Designation meeting with FDA regarding the clinical trial program. Palvella considered FDA feedback on study ethics and other considerations related to selection of key study design features, site feedback on study ethics and feasibility, and input from expert regulatory advisors, and Palvella initiated SELVA, a 24-week, pivotal Phase 3, single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin for the treatment of microcystic LMs, in the third quarter of 2024. The study's primary and key secondary endpoints are clinician-reported outcomes and will enroll 40 subjects at leading vascular anomaly centers across the U.S.

QTORIN™ Rapamycin for the Treatment of Cutaneous Venous Malformations

Palvella is also developing QTORIN™ rapamycin for the treatment of cutaneous venous malformations. Cutaneous venous malformations are a rare genetic disease that results from overactivation of the PI3K/mTOR signaling pathway in the development of the venous network, leading to dilated and dysfunctional veins within the skin. Cutaneous venous malformations cause functional impairment, significantly impact quality of life, and are associated with severe long-term complications. In April 2024, the FDA granted Fast Track Designation to QTORIN™ rapamycin for the treatment of venous malformations. Palvella plans to initiate a Phase 2 baseline-controlled clinical trial of QTORIN™ rapamycin for the treatment of cutaneous venous malformations in the second half of 2024.

About the Proposed Merger

Under the terms of the merger agreement, Pieris will issue shares of Pieris common stock to pre-merger Palvella stockholders as merger consideration in exchange for the cancellation of shares of capital stock of Palvella, and Palvella will become a wholly-owned subsidiary of Pieris.

Pre-merger Pieris stockholders are expected to own approximately 18% of the combined company and pre-merger Palvella stockholders are expected to own approximately 82% of the combined company, in each case, prior to the issuance of the shares under the 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 closing of the proposed transactions under the merger agreement, Pieris pre-merger stockholders will also be issued a contingent value right (CVR) representing the right to receive payments from proceeds received by the combined company, if any, under Pieris' existing partnership agreements with Pfizer and Boston Pharmaceuticals, in addition to other potential licensing agreements involving certain of Pieris' legacy assets, as well as certain potential payments related to historical research and development tax credits, which may or may not be realized.

The transactions contemplated by the merger agreement have been unanimously approved by the boards of directors of both companies and are expected to close in the fourth quarter of 2024, subject to approvals by the stockholders of each company, the effectiveness of a registration statement to be filed with the SEC to register the shares of Pieris common stock to be

issued in connection with the merger, and other customary closing conditions. Additional information about the transaction will be provided in a Current Report on Form 8-K that will be filed by Pieris with the SEC and will be available at www.sec.gov.

Management and Organization

Following the merger, the combined company will be led by Wes Kaupinen, Founder and CEO of Palvella, and other members of the Palvella management team. The combined company's board of directors will be comprised of four of the current directors of Palvella's board of directors, and one director designated from Pieris' current board of directors, who is expected to be Christopher Kiritsy, the chair of Pieris' audit committee. Pieris will be renamed "Palvella Therapeutics, Inc."

Conference Call Information

The companies will host a webcast call and presentation to discuss the proposed transactions, as well as Palvella's pipeline assets on Wednesday, July 24 at 8:30 am ET. The live webcast can be accessed here and on the Pieris website at www.pieris.com/investors in the 'Investors' section or by calling 877-407-8920 or +1 412-902-1010. A replay of the webcast will be archived and available following the event.

Advisors

TD Cowen is serving as lead placement agent and Cantor is serving as a placement agent for Palvella's planned concurrent financing. Troutman Pepper Hamilton Sanders LLP is serving as legal counsel to Palvella. Cooley LLP is serving as legal counsel to the placement agents. Stifel is serving as the exclusive financial advisor to Pieris and Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C. is serving as legal counsel to Pieris.

About Palvella Therapeutics

Founded and led by rare drug disease drug development veterans, Palvella Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no FDA-approved therapies. Palvella is developing a broad pipeline of product candidates based on its patented QTORIN™ platform, with an initial focus on serious, rare genetic skin diseases, many of which are lifelong in nature. Palvella's lead product candidate, QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), is currently in clinical development for microcystic lymphatic

malformations (microcystic LMs) and cutaneous venous malformations. QTORIN™ rapamycin has received FDA Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation for microcystic LMs, and Fast Track Designation for venous malformations. QTORIN™ rapamycin is for investigational use only and has not been approved or cleared by the FDA or by any other regulatory agency.

About Pieris Pharmaceuticals

Pieris is a biotechnology company based in Boston, Massachusetts that historically developed inhalable Anticalin proteins to treat respiratory diseases and locally-activated Mabcalin® (antibody-Anticalin®) bispecific proteins for immuno-oncology. Pieris' pipeline consists of clinical stage 4-1BB bispecific proteins that are currently being developed by Pfizer (formerly Seagen) and Boston Pharmaceuticals, along with other pre-clinical programs under development with Pfizer. Pieris could potentially be entitled to receive development, regulatory, and sales-based milestones from its partnered 4-1BB bispecific immuno-oncology assets.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (Securities Act)) concerning Palvella, Pieris, the proposed transactions, and other matters. These statements may discuss goals, intentions, and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Palvella and Pieris, as well as assumptions made by, and information currently available to, management of Palvella and Pieris. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements include, but are not limited to, expectations regarding the proposed merger transaction and concurrent private financing; the potential benefits and results of such transactions, including any potential benefits of the CVRs; the sufficiency of the combined company's capital resources; the combined company's cash runway; the expected timing of the closing of the proposed transactions; statements regarding the potential of, and expectations regarding, Palvella's 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 Palvella's Phase 2 clinical trial of QTORIN™ rapamycin in cutaneous venous malformations; Pieris' eligibility and potential to receive milestones from its partnered assets in connection with its contingent value rights; statements by Pieris' President and CEO; and statements by Palvella's Founder and CEO. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the limited operating history of each company; the significant net losses incurred since inception; the ability to raise additional capital to finance operations; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, Palvella's product candidates, including QTORIN™ rapamycin; the outcome of early clinical trials for Palvella's product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; the fact that data and results from clinical studies may not necessarily be indicative of future results; Palvella's limited experience in designing clinical trials and lack of experience in conducting clinical trials; the ability to identify and pivot to other programs, product candidates, or indications that may be more profitable or successful than Palvella's current product candidates; the substantial competition Palvella faces in discovering, developing, or commercializing products; the negative impacts of the global events on operations, including ongoing and planned clinical trials and ongoing and planned preclinical studies; the ability to attract, hire, and retain skilled executive officers and employees; the ability of Palvella and Pieris to protect their respective intellectual property and proprietary technologies; reliance on third parties, contract manufacturers, and contract research organizations; the risk that the conditions to the closing of the proposed transactions are not satisfied, including the failure to obtain stockholder approval for the proposed merger transaction from both Palvella's and Pieris' stockholders or to complete the proposed merger and concurrent private financing in a timely manner or at all; uncertainties as to the timing of the consummation of the proposed merger transaction and concurrent private financing transaction and the ability of each of the parties to consummate the proposed transactions; risks related to Pieris' continued listing on Nasdaq until closing of the proposed transaction; risks related to Palvella's and Pieris' ability to correctly estimate their respective operating expenses and expenses associated with the proposed transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined

company's cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement or the concurrent private financing transaction; competitive responses to the proposed transactions; risks related to the likelihood that the holders of CVRs will be entitled to any future payments; unexpected costs, charges or expenses resulting from the proposed transactions; the outcome of any legal proceedings that may be instituted against Palvella, Pieris, or any of their respective directors or officers related to the merger agreement, the concurrent private financing, or the proposed transactions contemplated thereby; the effect of the announcement or pendency of the proposed transactions on Palvella's and Pieris' business relationships, operating results and business generally; and legislative, regulatory, political and economic developments and general market conditions. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Pieris' most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC, as well as the registration statement on Form S-4 to be filed with the SEC by Pieris in connection with the merger. Palvella and Pieris can give no assurance that the conditions to the proposed transactions will be satisfied. Except as required by applicable law, Palvella and Pieris undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

No Offer or Solicitation

This press release is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, telephone and the internet) of interstate or

foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES OR DETERMINED IF THIS PRESS RELEASE IS TRUTHFUL OR COMPLETE.

Important Additional Information About the Proposed Transactions Will be Filed with the SEC

In connection with the proposed transaction between Pieris and Palvella, Pieris intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement and prospectus of Pieris and an information statement of Palvella. PIERIS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE MATERIALS, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT PIERIS, PALVELLA, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Pieris with the SEC (when they become available) through the website maintained by the SEC atwww.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Pieris with the SEC free of charge on Pieris' website at www.pieris.com, or by contacting Investor Relations by email at info@pieris.com. Investors and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Palvella, Pieris and their respective directors and executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about Pieris' directors and executive officers is included in Pieris' most recent Annual Report on Form10-K, as amended, including any information incorporated therein by reference, as filed with the SEC on March 29, 2024, and amended on April 29, 2024. Additional information regarding the persons who may be deemed participants in the solicitation of proxies will be included in the proxy statement/prospectus/information statement relating to the proposed

transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

Palvella Therapeutics Contact Information

Investors
Wesley H. Kaupinen
Founder and CEO, Palvella Therapeutics
info@palvellatx.com

Media
Marcy Nanus
Managing Partner, Trilon Advisors, LLC
mnanus@trilonadvisors.com

Pieris Pharmaceuticals Contact Information

Investors
info@pieris.com