Palvella Therapeutics Announces Closing of Merger with Pieris Pharmaceuticals and Concurrent Private Placement of $78.9 Million

December 13, 2024

Palvella Therapeutics to debut on Nasdaq under the ticker symbol "PVLA" as a publicly traded rare disease biopharmaceutical company advancing a late clinical-stage pipeline and a platform for treating serious, rare genetic diseases

Strong balance sheet with approximately $80.0 million of cash and cash equivalents, including proceeds from a PIPE financing co-led by BVF Partners, L.P. and Frazier Life Sciences

Cash expected to fund operations into the second half of 2027, including through Phase 3 SELVA clinical trial of QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatmer of microcystic lymphatic malformations (microcystic LMs) and Phase 2 clinical trial in cutaneous venous malformations (cutaneous VMs)

Microcystic LMs is a chronically debilitating and lifelong genetic disease affecting an estimated more than 30,000 diagnosed patients in the U.S.

QTORIN™ rapamycin has the potential to be the first approved therapy and standard of care in the U.S. for microcystic LMs and cutaneous VMs

WAYNE, Pa., Dec. 13, 2024 (GLOBE NEWSWIRE) -- 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, today announced the completion of its previously announced merger with Pieris Pharmaceuticals, Inc. (Pieris). The combined company will operate under the name Palvella Therapeutics, Inc., and its shares are expected to begin trading on the Nasdaq Capital Market on December 16, 2024, under the ticker symbol "PVLA". Palvella will continue to be led by Wes Kaupinen, its Founder and Chief Executive Officer, and other members of the Palvella management team. The transaction was approved by Pieris stockholders at a special meeting held on December 11, 2024, and the transaction had been previously approved by Palvella stockholders.

"With strong support from leading healthcare-dedicated investors, Palvella is well positioned to

enter the public markets 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 Mr. Kaupinen. “This transaction will enable us to accelerate late-stage development of QTORIN™ rapamycin, our lead product candidate, for microcystic LMs and cutaneous VMs while also further advancing additional novel product candidates from our QTORIN™ platform."

Concurrent with the merger, Palvella completed a previously announced oversubscribed $78.9 million private placement co-led by BVF Partners, L.P., an existing investor, and Frazier Life Sciences, a new investor, and with participation from a syndicate of leading healthcare-dedicated investors. 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, Integrated Finance Group (an AscellaHealth partner company), BioAdvance, and Gore Range Capital also participated in the financing. Palvella's cash and cash equivalents of approximately $80.0 million is expected to fund operations into the second half of 2027, including through results from the SELVA Phase 3 clinical trial of QTORIN™ rapamycin for the treatment of microcystic LMs and Phase 2 clinical trial of QTORIN™ rapamycin in cutaneous VMs.

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. Well-accepted mechanisms of action of rapamycin and 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. Palvella’s QTORIN™ product candidates are designed for targeted, localized delivery of therapeutic agents to pathogenic tissue of interest while minimizing systemic absorption and thereby reducing the risk of unwanted adverse events associated with systemic therapy.

Palvella's lead product candidate QTORIN™ rapamycin is a novel, patented 3.9% rapamycin anhydrous gel currently under development for the treatment of microcystic LMs, cutaneous VMs, and other serious, functionally debilitating skin diseases driven by the overactivation of the mammalian target of rapamycin (mTOR) pathway. QTORIN™ rapamycin has received FDA Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation for microcystic LMs and is the recent recipient of up to a $2.6 million FDA Orphan Products Grant. QTORIN™ rapamycin has also received Fast Track Designation for venous malformations. QTORIN™ rapamycin is protected by issued composition patents covering anhydrous gel

formulations of rapamycin, as well as methods of use, in the U.S., Japan, Australia, China and Israel and pending patent applications broadly covering anhydrous gel formulations of rapamycin, as well as methods of use, in the U.S. and other countries.

In the third quarter of 2024, Palvella initiated SELVA, a 24-week, Phase 3, single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin administered once daily for the treatment of microcystic LMs. The primary efficacy endpoint is the change from baseline in the overall microcystic LM Investigator Global Assessment (mLM-IGA) at week 24. The Phase 3 study is enrolling approximately 40 subjects, age six or older, at leading vascular anomaly centers across the U.S.

Transaction Details

Based on the final exchange ratio of approximately 0.30946 shares of Pieris common stock for each share of Palvella common stock, at the closing of the merger, there are approximately 13.95 million shares of the combined company's common stock outstanding on a diluted basis, with prior Pieris stockholders owning approximately 11% on a diluted basis and prior Palvella stockholders (including investors in the private placement) holding approximately 89% of the combined company's outstanding common stock on a diluted basis.

In connection with the closing of the merger, Pieris issued a non-transferable contingent value right (CVR) to Pieris shareholders of record immediately prior to the closing, which does not include the former holders of shares of Palvella or the private financing investors. Holders of the CVR will be entitled 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.

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

About Microcystic Lymphatic Malformations

Microcystic LMs are 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 that can cause hospitalization. The natural history of microcystic LMs are persistent and progressive without spontaneous resolution, 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.

About Palvella Therapeutics

Founded and led by rare drug disease drug development veterans, Palvella Therapeutics (Nasdaq: PVLA) 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 the Phase 3 SELVA clinical trial in microcystic lymphatic malformations (microcystic LMs) and a Phase 2 trial in cutaneous venous malformations. For more information, please visit www.palvellatx.com or follow the Company on LinkedIn.

QTORIN™ rapamycin is for investigational use only and has not been approved or cleared by the FDA or by any other regulatory agency.

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)). 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, 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. 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 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 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.

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