Soligenix Investor Relations

Soligenix Announces Recent Accomplishments and Year End 2024 Financial Results

PRINCETON, N.J., March 21, 2025 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, announced today its recent accomplishments and financial results for the year ended December 31, 2024.

"We remain highly focused on advancing our multiple clinical programs as we work towards achieving a number of important and potentially transformational development milestones, including top-line results in 2026 for our actively enrolling confirmatory Phase 3 placebo-controlled study evaluating HyBryte™ (synthetic hypericin) in the treatment of early-stage cutaneous T-cell lymphoma (CTCL)," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. In the second half of this year, we also anticipate reporting top-line results from our ongoing Phase 2 studies for SGX945 (dusquetide) in Behçet's disease and SGX302 (synthetic hypericin) in mild-to-moderate psoriasis."

Dr. Schaber continued, "With approximately $7.8 million in cash at December 31, 2024, we are committed to disciplined resource allocation to achieve our strategic goals. While this cash balance provides operating runway through 2025, we continue to evaluate all strategic options, including partnership, merger and acquisition, government grants, and potential financing opportunities to advance our late-stage pipeline and the Company."

Soligenix Recent Accomplishments

- On January 14, 2025, the Company reported positive outcomes observed from the interim update on the open-label, investigator-initiated study (IIS) evaluating extended HyBryte™ treatment for up to 12 months in patients with early-stage CTCL. To view this press release, please click here.
- On December 16, 2024, the Company announced that it had opened patient enrollment for its confirmatory Phase 3 study evaluating HyBryte™ in the treatment of CTCL. To view this press release, please click here.
- On December 2, 2024, the Company announced analysis of the post-treatment data from the open-label study (protocol HPN-CTCL-04) comparing HyBryte™ to Valchlor® (mechlorethamine) demonstrating continued improvement in HyBryte™ treated patients and their individual lesions even after stopping treatment. To view this press release, please click here.
- On November 19, 2024, the Company announced the formation of a European Medical Advisory Board (MAB) to provide additional medical/clinical strategic guidance to the Company as it advances its confirmatory Phase 3 multicenter, double-blind, placebo-controlled study evaluating the safety and efficacy of HyBryte™ in the treatment of CTCL patients with early-stage disease. To view this press release, please click here.
- On November 14, 2024, the Company announced it had opened patient enrollment for its Phase 2 study (protocol number DUS-AUBD-01) evaluating SGX945 (dusquetide) in the treatment of Behçet's Disease. To view this press release, please click here.

Financial Results – Quarter Ended December 31, 2024

Soligenix reported revenues of $0.1 million for the year ended December 31, 2024, compared to $0.8 million for the prior year. The decrease was primarily due to the timing of government grant funding and contracts supporting the development of SGX943 for emerging infectious diseases, as well as the development of CiVax™ and HyBryte™. While we continue to receive government funding, fluctuations in grant timing may impact quarterly and annual revenues.

Soligenix's net loss was $8.3 million, or ($4.98) per share, for the year ended December 31, 2024, compared to $6.1 million, or ($12.66) per share, for the prior year. The change in net loss per share reflects the Company's one-for-sixteen reverse stock split, which was completed in June 2024. The overall increase in net loss was primarily due to lower revenue, higher research and development expenses associated with clinical trial activities, and changes in tax benefits, partially offset by increased interest income, tax credits and the change in the fair value of debt.

Research and development expenses were $5.2 million as compared to $3.3 million for the years ended December 31, 2024 and 2023, respectively. The increase was primarily related to preliminary costs associated with the initiation of our Phase 2 study in Behçet's Disease and the second confirmatory Phase 3 CTCL trial offset by an adjustment of estimated accruals for completed clinical trials.

General and administrative expenses were $4.2 million and $4.5 million for the years ended December 31, 2024 and 2023, respectively. The decrease in general and administrative expenses for the three months ended December 31, 2024 was primarily attributable to decreases in legal and consulting expenses.

As of December 31, 2024, the Company's cash position was approximately $7.8 million.

About Soligenix, Inc.

Soligenix is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. Our Specialized BioTherapeutics business segment is developing and moving

toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin sodium) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer, and (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, as well as our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID), the Defense Threat Reduction Agency (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website athttps://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

This press release may contain forward-looking statements that reflect Soligenix's current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations, clinical trial enrollment, the expected timing for closing the offering described herein and the intended use of proceeds therefrom. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements, and include the expected amount and use of proceeds from the offering and the expected closing date of the offering. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the U.S. Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 2a clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission (the "SEC"), including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

SOURCE SOLIGENIX, INC.

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