Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Third Quarter 2024 Financial Results

PRINCETON, N.J., Nov. 8, 2024 /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 quarter ended September 30, 2024.

"We remain focused on multiple clinical activities and upcoming milestones, including the initiation of our confirmatory Phase 3 placebo-controlled study evaluating HyBryte™ (synthetic hypericin) in the treatment of early-stage cutaneous T-cell lymphoma (CTCL) before yearend," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. Additionally, we are set to initiate a Phase 2 study for SGX945 (dusquetide) in Behçet's disease shortly, with top-line results expected in the first half of 2025, which will be accompanied by data readout from our ongoing SGX302 (synthetic hypericin) Phase 2 study in mild-to-moderate psoriasis in the first half as well."

Dr. Schaber continued, "With approximately $9.8 million in cash at September 30, 2024, we continue to prioritize resource allocation to achieve our goals. While we remain focused on our future, we are diligently pursuing strategies to enhance long-term shareholder value, including strategic partnerships and mergers and acquisitions."

Soligenix Recent Accomplishments

- On October 22, 2024, the Company announced that the Hong Kong Patent Office had granted the patent entitled "Systems and Methods for Producing Synthetic Hypericin", allowing claims for a novel proprietary process of producing highly purified synthetic hypericin. To view this press release, please click here.
- On October 7, 2024, the Company announced its lead investigators from the University of Pennsylvania and the Rochester Skin Lymphoma Medical Group would present findings from recent supportive studies with HyBryte™ in the treatment of CTCL at the European Organisation for Research and Treatment of Cancer. To view this press release, please click here.
- On October 3, 2024, the Company announced it has established a partnership agreement with Sterling Pharma Solutions to optimize and implement a commercially viable, scalable production technology for synthetic hypericin. To view this press release, please click here.
- On September 3, 2024, the Company announced the European Patent Office had granted the patent entitled "Systems and Methods for Producing Synthetic Hypericin", allowing claims for a novel proprietary process of producing highly purified synthetic hypericin. To view this press release, please click here.

Financial Results – Quarter Ended September 30, 2024

Soligenix received no revenue for the quarter ended September 30, 2024 as compared to $0.1 million for the quarter ended September 30, 2023. Revenues primarily relate to government contracts, grants and subawards awarded in support of SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; development of CiVax™, our vaccine candidate for the prevention of COVID-19, and evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL.

Soligenix's net loss was $1.7 million for the quarters ended September 30, 2024 and 2023, or ($0.78) per share and ($2.56) per share, respectively. This increase in net loss was primarily due to decreases in gross profit and tax credits as well as an increase in operating expenses, offset by increases in interest income and the change in the fair value of debt during the three months ended September 30, 2024.

Research and development expenses were $1.0 million as compared to $0.8 million for the quarters ended September 30, 2024 and 2023, respectively. The increase was preliminary due to 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 $0.9 million and $1.0 million for the quarters ended September 30, 2024 and 2023, respectively. The decrease in general and administrative expenses for the three months ended September 30, 2024 was primarily attributable to decreases in legal and professional fees.

As of September 30, 2024, the Company's cash position was approximately $9.8 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.

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