Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And First Quarter 2025 Financial Results

PRINCETON, N.J., May 9, 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 quarter ended March 31, 2025.

"Our strategic focus remains on advancing our clinical programs, and we anticipate several significant development milestones. These include top-line results in 2026 from our actively enrolling Phase 3 confirmatory study of HyBryte™ (synthetic hypericin) for early-stage cutaneous T-cell lymphoma (CTCL). Furthermore, we expect to report top-line results in the second half of this year from our ongoing Phase 2 studies of SGX945 (dusquetide) in Behçet's disease and SGX302 (synthetic hypericin) in mild-to-moderate psoriasis," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix.

Dr. Schaber continued, "With approximately $7.3 million in cash at March 31, 2025, we are committed to allocating resources responsibly to achieve our strategic goals and near-term milestones. While this cash balance provides sufficient operating runway through December 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 April 14, 2025, the Company announced positive interim results following 18 weeks of treatment from the ongoing open-label, investigator-initiated study (IIS) evaluating extended HyBryte™ treatment for up to 54 weeks in patients with early-stage CTCL. To view this press release, please click here.
- On March 25, 2025, the Company announced a publication describing the preclinical efficacy of CiVax™, a thermostabilized subunit vaccine against SARS-CoV-2. To view the publication, please click here. To view this press release, please click here.

Financial Results – Quarter Ended March 31, 2025

Soligenix reported no revenue for the quarter ended March 31, 2025, compared to $0.1 million for the prior quarter ended March 31, 2024. The decrease was primarily related to a decrease in revenue associated with the zero-margin grant for the HyBryte™ IIS.

Soligenix's net loss was $3.2 million, or ($1.06) per share, for the quarter ended March 31, 2025, compared to $1.9 million, or ($2.91) per share, for the quarter ended March 31, 2024. This increase in net loss was primarily due to an increase in operating expenses related to ongoing clinical trials and a decrease in other income attributable to the change in the fair value of debt during the three months ended March 31, 2024 with no corresponding change in fair value during the three months ended March 31, 2025.

Research and development expenses were $2.2 million for the quarter ended March 31, 2025 as compared to $1.1 million for the same period in 2024. The increase was primarily due to costs associated with our Phase 2 study in Behçet's Disease and the second confirmatory Phase 3 CTCL trial as well as increases in third party manufacturing.

General and administrative expenses were $1.1 million for the quarter ended March 31, 2025 as compared to $1.0 million for the same period in 2024. The increase was primarily attributable to increases in professional expenses and various taxes.

As of March 31, 2025, the Company's cash position was approximately $7.3 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) 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 for the treatment of inflammatory diseases, including oral mucositis in head and neck cancer (SGX942), and in Behçet's Disease (SGX945).

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. 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. 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 or any other studies (including the open-label, investigator-initiated study), 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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