Soligenix Investor Relations

Soligenix Announces Recent Accomplishments and Third Quarter 2025 Financial Results

PRINCETON, N.J., Nov. 7, 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 September 30, 2025.

"We remain focused on multiple upcoming milestones before year-end, including top-line results from our Phase 2a clinical trial in mild-to-moderate psoriasis with SGX302 (synthetic hypericin) and an enrollment update for the confirmatory Phase 3 study evaluating HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL)," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Recently, we were pleased to announce that the first Data Monitoring Committee (DMC) meeting for the confirmatory Phase 3 study evaluating HyBryte™ in the treatment of CTCL had concluded that there were no safety concerns, with HyBryte™ demonstrating an acceptable safety profile that remains consistent with the safety data from all prior clinical studies. Looking ahead to 2026, Phase 3 enrollment remains on track with top-line results anticipated in the second half of 2026."

Dr. Schaber continued, "With approximately $10.5 million in cash at September 30, 2025, we're focused on carefully allocating resources to hit our strategic goals and upcoming milestones. While this cash balance provides sufficient operating runway through 2026, 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 October 14, 2025, the Company announced the update of itsUnited States (U.S.) Medical Advisory Board (MAB) for CTCL to provide medical/clinical strategic guidance to the Company as it advances the Phase 3 clinical development of HyBryte™. To view this press release, please click here.
- On October 7, 2025, the Company announced its first DMC meeting for its confirmatory Phase 3 study evaluating HyBryte™ in the treatment of CTCL had concluded that there were no safety concerns and that HyBryte™ has an acceptable safety profile that remains consistent with the safety data from all prior clinical studies. To view this press release, please click here.
- On September 30, 2025, the Company announced the expansion of its European MAB to provide additional medical/clinical strategic guidance to the Company as it advances its confirmatory Phase 3 d study evaluating the safety and efficacy of HyBryte™. To view this press release, please click here.
- On September 29, 2025, the Company announced the closing of its previously announced public offering with participation from existing and certain healthcare focused institutional investors. To view this press release, please click here.
- On September 23, 2025, the Company announced the appointment of Tomas J. Philipson, PhD as a Strategic Advisor, given his extensive experience and relationships at the highest levels of government, including with U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services. To view this press release, please click here.
- On September 4, 2025, the Company announced a publication describing the extended stability of ebolavirus vaccines using its ThermoVax® platform. To view this press release, please clickhere.
- On August 18, 2025, the Company announced that the Office of Orphan Products Development of the FDA had granted orphan drug designation to dusquetide, the active ingredient in SGX945, for "treatment of Behçet's Disease" following review of positive Phase 2a clinical results demonstrating biological efficacy and safety in patients with Behçet's Disease. To view this press release, please click here.

Financial Results – Quarter Ended September 30, 2025

Soligenix reported no revenue for the quarters ended September 30, 2025 and 2024.

Soligenix's net loss was $2.5 million, or ($0.58) per share, for the quarter endedSeptember 30, 2025, compared to $1.7 million, or ($0.78) per share, for the quarter endedSeptember 30, 2024. This increase in net loss was primarily due to an increase in operating expenses related to ongoing clinical trials and a decrease in interest income and a CARES Act employee retention credit received during the three months ended September 30, 2024 with no corresponding employee retention credit received during the three months ended September 30, 2025.

Research and development expenses were $1.6 million for the quarter ended September 30, 2025 as compared to $1.0 million for the same period in 2024. The increase was primarily due to costs associated with the second confirmatory Phase 3 CTCL trial as well as increases in third party contract manufacturing.

General and administrative expenses were $1.0 million for the quarter ended September 30, 2025 as compared to $0.9 million for the same period in 2024. The decrease was primarily attributable to increases in professional expenses.

As of September 30, 2025, the Company's cash position was approximately$10.5 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 at https://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

This press release may contain forward-looking statements that reflect the Company's current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations, and 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 SEC, including, but not limited to, the Company'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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