Soligenix Investor Relations

Soligenix Announces Recent Updates and First Quarter 2026 Financial Results

PRINCETON, N.J., May 8, 2026 /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 updates and financial results for the quarter ended March 31, 2026.

"We remain disappointed with the unanticipated outcome of the FLASH2 (Fluorescent Light Activated Synthetic Hypericin 2) study," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Despite the fact that HyBryte™ (synthetic hypericin) demonstrated statistically significant reductions in cutaneous T-cell lymphoma (CTCL) lesions after 6 weeks treatment in the first FLASH study, a similar signal was not observed with 18 weeks of treatment in this study. Over the coming weeks, we will analyze the data to better determine why the study did not meet expectations. If there is any clarity gained from further analysis of the dataset, especially with respect to specific subsets of patients that may benefit from HyBryte™ therapy, then we intend to communicate our findings and explore follow-up discussions with the European Medicines Agency (EMA) and the Food and Drug Administration (FDA)."

With approximately $6.0 million in cash at March 31, 2026, and cash runway into the 2nd quarter of 2027, we will evaluate all strategic options moving forward, including but not limited to merger and acquisition opportunities, and the potential of advancing SGX945 (dusquetide) for the treatment of Behçet's Disease, which demonstrated promising biological efficacy in a Phase 2 study last year while most recently receiving orphan drug designation from EMA and Promising Innovative Medicine (PIM) designation from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA). In December, we announced the extended results of the Phase 2a trial of SGX302 (synthetic hypericin) for the treatment of mild-to-moderate psoriasis where SGX302 gel therapy was well tolerated by all patients with no drug related adverse events identified. With the completion of the pilot study, we have laid the groundwork for a more detailed evaluation in this large underserved market.

Soligenix Recent Updates

- On April 28, 2026, the Company announced that the Data Monitoring Committee completed the interim efficacy analysis of its pivotal Phase 3 FLASH2 trial evaluating HyBryte™ in the treatment of CTCL and recommended the study halt for futility. To view this press release, please click here.
- On April 2, 2026, the Company announced that the positive results of its comparability study evaluating HyBryte™ versus Valchlor® (mechlorethamine) for the treatment of CTCL have been published in *Oncology and Therapy*. To view this press release, please click here.

Financial Results – Quarter Ended March 30, 2026

Soligenix had no revenue or related costs for the quarter ended March 31, 2026 and 2025, respectively.

Soligenix's net loss was $2.8 million, or ($0.28) per share, for the quarter ended March 31, 2026, compared to $3.0 million, or ($0.97) per share, for the same prior year period. This decrease in net loss was primarily due to a decrease in operating expenses.

Research and development expenses were $1.8 million as compared to $1.9 million for the quarter ended March 31, 2026 and 2025, respectively. The decrease was primarily due to decreases in costs associated with third-party manufacturing, the completed Phase 2 study in BD and site initiation fees for the second confirmatory Phase 3 CTCL trial, partially offset by an increase in patient fees for the second confirmatory Phase 3 CTCL trial.

General and administrative expenses were $1.1 million for the quarter ended March 31, 2026 as compared to $1.1 million for the same period in 2025, relatively flat with a de minimis increase.

As of March 31, 2026, the Company's cash position was approximately $6.0 million.

About Soligenix, Inc.

Soligenix is a 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 synthetic hypericin for the treatment of psoriasis (SGX302), and our first-in-class Innate Defense Regulator (IDR) technology, dusquetide, for the treatment of inflammatory diseases, including aphthous ulcers in Behçet's Disease (BD) (SGX945) and oral mucositis in head and neck cancer (SGX942). We were developing HyBryte™ (SGX301 or synthetic hypericin sodium), a photodynamic therapy utilizing visible light, for the treatment of cutaneous T-cell lymphoma (CTCL) in a Phase 3 study called "FLASH2" (Fluorescent Light Activated Synthetic Hypericin 2). The Data Monitoring Committee completed its interim efficacy analysis of the FLASH2 trial during April 2026, and under the terms of the interim analysis, the study was recommended to halt for futility. We are in the process of analyzing the data to better determine why the study did not meet expectations.

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 X 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 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, and include the expected timing and results of clinical trials and the expected timing of regulatory submissions and approvals. In light of the discontinuation of the FLASH2 study, the Company's ability to continue as a going concern will be dependent upon its ability to develop and commercialize its remaining pipeline assets, including dusquetide for the treatment of Behçet's Disease, to identify and acquire or in-license additional product candidates or technologies, and to raise sufficient capital to fund such development and any such acquisitions. There can be no assurance that the Company will be able to obtain financing on acceptable terms, if at all, that suitable acquisition or in-licensing opportunities will be available, or that any of its remaining or future development programs will be successful. If the Company is unable to raise sufficient capital or otherwise advance its remaining assets, it may be required to significantly curtail or cease its operations, sell or otherwise dispose of its assets, or pursue dissolution and liquidation. 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) and the overall blinded study response rate observed in the second HyBryte™ (SGX301) Phase 3 clinical trial, notwithstanding any prior observations regarding such blinded response rate, the second HyBryte™ (SGX301) Phase 3 clinical trial did not demonstrate sufficient efficacy at the interim analysis to support continuation of the study, and no assurance can be given that any further development of HyBryte™ (SGX301) will be pursued or that a marketing authorization from the FDA or EMA will be sought or granted. Notwithstanding the result of HyBryte™ (SGX301) in the first Phase 3 clinical trial (or any other studies) 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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