

## Soligenix Announces Recent Accomplishments And Second Quarter 2024 Financial Results

PRINCETON, N.J., Aug. 9, 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 June 30, 2024.

"This is a pivotal time for Soligenix with a great deal of clinical activity and upcoming milestones," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "While we prepare for the upcoming initiation of our [confirmatory Phase 3 placebo-controlled](#) study evaluating the safety and efficacy of HyBryte™ (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL) patients with early-stage disease, we are incredibly encouraged by the recent [positive clinical results](#) from our comparability study evaluating HyBryte™ against Valchlor® (mechlorethamine gel), which demonstrated a three-fold higher response rate over a 12-week treatment period and more favorable safety profile for HyBryte™ in the treatment of CTCL. These findings, coupled with the [promising interim data](#) from the ongoing open-label, investigator-initiated study evaluating extended HyBryte™ treatment, reinforce our excitement about the future of HyBryte™ as a potential front-line treatment option for patients with early-stage CTCL. Additionally, we will be initiating a Phase 2 study with SGX945 (dusquetide) in Behçet's disease later this year with top-line results expected in the first half of 2025, along with top-line results expected during the same timeframe from our ongoing SGX302 (synthetic hypericin) Phase 2 study in mild-to-moderate psoriasis."

Dr. Schaber continued, "With approximately \$9.1 million in cash at June 30, 2024, exclusive of the approximately \$4.1 million in net proceeds from recent warrant exercises, we continue to prioritize resource allocation to achieve our goals. We have a clear vision for the future, and we are actively pursuing strategies to create long-term value for our shareholders, including but not limited to, partnership and merger and acquisition opportunities."

### Soligenix Recent Accomplishments

- On July 24, 2024, the Company received a letter from Nasdaq confirming that the Company had regained compliance with the Minimum Bid Price Rule. Accordingly, the Nasdaq Hearings Panel determined to continue the listing of the Company's common stock and closed the matter.
- On July 9, 2024, the Company announced an interim update on the open-label, investigator-initiated study evaluating extended HyBryte™ treatment for up to 12 months in patients with early-stage CTCL. To view this press release, please click [here](#).
- On June 25, 2024, the Company announced positive clinical results from a comparability study evaluating HyBryte™ versus Valchlor® in the treatment of CTCL. To view this press release, please click [here](#).
- On May 16, 2024, the Company announced the publication of results of its compatibility study evaluating HyBryte™ for the treatment of CTCL in the Journal of the European Academy of Dermatology & Venereology (JEADV) Clinical Practice. To view the publication, please click [here](#). To view this press release, please click [here](#).

### Financial Results – Quarter Ended June 30, 2024

Soligenix's revenues for the quarter ended June 30, 2024 were less than \$0.1 million as compared to \$0.2 million for the quarter ended June 30, 2023. Revenues primarily relate to government contracts and grants 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 \$1.6 million, or (\$1.31) per share, for the quarter ended June 30, 2024, as compared to \$1.6 million, or (\$3.56) per share, for the quarter ended June 30, 2023. The 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 changes in the fair value of debt during the three months ended June 30, 2024.

Research and development expenses were \$0.5 million as compared to \$0.8 million for the quarters ended June 30, 2024 and 2023, respectively. The decrease was primarily due to adjustment of estimated accruals for completed clinical trials offset by preliminary costs associated with the anticipated initiation of our Phase 2 study in Behçet's Disease and the second Phase 3 CTCL trial.

General and administrative expenses were \$1.2 million and \$0.9 million for the quarters ended June 30, 2024 and 2023, respectively. The increase in general and administrative expenses for the three months ended June 30, 2024 was primarily attributable to an increase in legal and professional fees associated with the 2024 annual meeting of stockholders, the April 2024 public offering and the June 2024 reverse stock split of our issued and outstanding shares of common stock.

As of June 30, 2024, the Company's cash position, exclusive of the approximately \$4.1 million in net proceeds from recent warrant exercises, was approximately \$9.1 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 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. 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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