Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Year-End 2021 Financial Results

PRINCETON, N.J., March 29, 2022 /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 year ended December 31, 2021.

"This year will be a pivotal year for the Company as we anticipate achieving a number of transformational milestones," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Most importantly, these milestones include submission of the new drug application (NDA) to the United States (U.S.) Food and Drug Administration (FDA) for marketing authorization of HyBryte™ (SGX301 or synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL), a rare form of skin cancer. Additionally, we anticipate initiating a Phase 2a clinical trial in mild-to-moderate psoriasis with SGX302 (synthetic hypericin), where we have already demonstrated positive proof of concept in a small Phase 1/2 pilot study. Under our Public Health Solutions business segment, we continue to advance our heat stable vaccine platform technology, ThermoVax®, including through development of filovirus vaccine candidates (targeting Ebola, Sudan, and Marburg viruses), a novel heat stable COVID-19 vaccine candidate, CiVax™, and a ricin toxin vaccine, RiVax®, where non-human primate (NHP) data for all three vaccine programs has demonstrated significant efficacy."

Dr. Schaber continued, "With approximately $23.3 million in cash, not including our non-dilutive government funding, we expect to have the capital required to accomplish our near-term milestones, including NDA filing and expansion into psoriasis with the conduct of the Phase 2a clinical trial. We continue to evaluate various strategic options, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On March 17, 2022, the Company announced the results of a booster vaccination study using CiVax™ (heat stable COVID-19 subunit vaccine program) in NHPs demonstrating rapid enhancement of neutralizing antibody responses to SARS-CoV-2, including against Delta and Omicron variants. To view this press release, please click here.
- On January 10, 2022, the Company issued an update letter from its President and Chief Executive Officer, Dr. Christopher J. Schaber. To view this press release, please click here.
- On January 4, 2022, the Company announced that dusquetide is effective at reducing tumor size in nonclinical xenograft models. To view this press release, please click here.
- On December 2, 2021, the Company announced 100% protection of NHPs against lethal Sudan ebolavirus challenge using a bivalent, thermostabilized vaccine formulated in a single vial, reconstituted only with water immediately prior to use. To view this press release, please click here.

Financial Results – Year Ended December 31, 2021

Soligenix's revenues for the year ended December 31, 2021 were $0.8 million as compared to $2.4 million for the year ended December 31, 2020. Revenues primarily included payments on grants received to support the development of: SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; ThermoVax®, our thermostabilization platform technology; and CiVax™, our vaccine candidate for the prevention of COVID-19.

Soligenix's basic net loss was $12.6 million, or ($0.31) per share, for the year ended December 31, 2021, as compared to $17.7 million, or ($0.64) per share, for the year ended December 31, 2020. The decrease in net loss is primarily due to the additional costs in 2020 relating to the issuance of $5.0M worth of fully vested shares of common stock to Hy Biopharma, Inc. ("Hy Biopharma") in connection with the achievement of a development milestone.

Research and development expenses were $8.4 million as compared to $9.8 million for the years ended December 31, 2021 and 2020, respectively. The decrease in research and development spending for the year ended December 31, 2021 was related to the conclusion of the CTCL and oral mucositis Phase 3 studies.

General and administrative expenses were $4.8 million and $4.3 million for the years ended December 31, 2021 and 2020, respectively. This increase in general and administrative expenses is primarily due to an increase in legal fees associated with the Emergent arbitration partially offset by a decrease in company headcount.

As of December 31, 2021, the Company's cash position was approximately $26.0 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 a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. 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 proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and 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, Inc.'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, such as experienced with the COVID-19 outbreak. 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 HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept 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, 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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