Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Second Quarter 2021 Financial Results

PRINCETON, N.J., Aug. 13, 2021 /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, 2021.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "2021 remains a crucial year for Soligenix. Under our Specialized BioTherapeutics business segment, our HyBryte™ (SGX301) positive pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study in cutaneous T-cell lymphoma (CTCL) was recently selected for presentation at the United States Cutaneous Lymphoma Consortium (USCLC) Annual Meeting. Additionally, HyBryte™ received a Pediatric Investigation Plan (PIP) waiver from the European Medicines Agency (EMA), which is a key component of the regulatory process for marketing authorization in Europe. We continue to move our pipeline forward with multiple data readouts expected this year under our Public Health Solutions business segment. This data is critial in our efforts to advance our therapeutic and vaccine candidates such as CiVax™, our heat stable COVID-19 vaccine."

Dr. Schaber continued, "With approximately $29 million in cash, not including our non-dilutive government funding, we anticipate having sufficient capital to achieve multiple inflection points as we advance our rare disease pipeline, including NDA filing in the first half of 2022 and U.S. commercialization of HyBryte™ in CTCL, where we estimate peak U.S. annual net sales to exceed $90 million and the total U.S. revenues during the 10-year forecast period to be greater than $700 million. We are also aggressively exploring and evaluating multiple strategic options moving forward, including but not limited to, partnership and merger and acquisition opportunities."

Soligenix Recent Accomplishments

- On June 22, 2021, the Company announced that Ellen Kim, MD, Medical Director, Dermatology Clinic, Perelman Center for Advanced Medicine, Professor of Dermatology at the Hospital of the University of Pennsylvania, and the Lead Principal Investigator for the Phase 3 FLASH study in CTCL, would present key details of HyBryte™ (hypericin ointment 0.25%) efficacy and safety profile demonstrated in the FLASH study at the USCLC Annual Meeting, to be held on June 26, 2021. To view this press release, please click here.
- On June 10, 2021, the Company announced that it had received a PIP waiver from the EMA for HyBryte™, which has recently and successfully concluded a Phase 3, pivotal clinical study for the treatment of early stage CTCL. To view this press release, please click here.
- On June 9, 2021, the Company announced that it had received approximately $865,000, net of transaction costs, in non-dilutive financing via the state of New Jersey's Technology Business Tax Certificate Transfer Program. To view this press release, please click here.
- On May 20, 2021, the Company announced that the Japan Patent Office had allowed the patent application titled "Systems and Methods for Producing Synthetic Hypericin". The allowed claims are directed to unique, proprietary methods to produce a novel, highly purified form of synthetic hypericin, and are similar to those previously allowed in the United States. To view this press release, please click here.

Financial Results – Quarter Ended June 30, 2021
Soligenix's revenues for the quarter ended June 30, 2021 were $0.2 million as compared to $0.5 million for the quarter ended June 30, 2020. Revenues included payments on grants received to support the development of: SGX943 for treatment of emerging and/or antibiotic-resistant infectious diseases; ThermoVax®, our thermostabilization technology; and CiVax™, our vaccine candidate for the prevention of COVID-19.

Soligenix's basic net loss was $1.9 million, or ($0.05) per share, for the quarter ended June 30, 2021, as compared to $2.8 million, or ($0.10) per share, for the quarter ended June 30, 2020. This decrease in net loss was primarily due to the gain on the forgiveness of the Payroll Protection Program loan and the sale of New Jersey NOL carryforwards offset by reduced contract revenues and the interest expense on convertible debt.

Research and development expenses were $2.1 million as compared to $2.2 million for the quarters ended June 30, 2021 and 2020, respectively. The decrease in research and development spending for the quarter ended June 30, 2021 was primarily attributable to the reduction in expense due to the completion of the HyBryte™ and SGX942 clinical trials.

General and administrative expenses were $0.9 million and $0.8 million for the three months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, the Company's cash position was approximately $29.0 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 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. 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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