Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Year-End 2018 Financial Results

PRINCETON, NJ – March 26, 2019 – 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, 2018.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, “We are actively enrolling patients in our pivotal double-blind, placebo-controlled Phase 3 clinical trial of SGX942 (dusquetide) for the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. We anticipate completion of patient enrollment for the planned interim analysis in the first half of 2019, with the results of the interim analysis expected in the third quarter of 2019.”

Dr. Schaber continued, “Following the positive recommendation received from the independent Data Monitoring Committee (DMC), we continue to enroll patients in our double-blind, placebo-controlled Phase 3 study for the treatment of cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), for which we expect final results in the first quarter of 2020.”

Soligenix Recent Accomplishments:

- On February 11, 2019, the Company announced the allowance of a new United States (US) patent protecting its ricin toxin vaccine, RiVax®. The patent, titled “Multivalent Stable Vaccine Composition and Methods of making same”, supports combination vaccines protecting against ricin intoxication as well as other toxins, such as those associated with anthrax. To view this press release, please click here.
- On February 7, 2019, the Company announced publication of a scientific article demonstrating the successful thermostabilization of an Ebola subunit vaccine candidate. The article titled, “Thermostable Ebola virus vaccine formulations lyophilized in the presence of aluminum hydroxide”, is published in the European Journal of Pharmaceutics and Biopharmaceutics online. To view this press release, please click here.
- On January 23, 2019, the Company announced that the European Patent Office had granted the patent entitled “Novel Peptides for Treating and Preventing Immune-Related Disorders, Including Treating and Preventing Infection by Modulating Innate Immunity.” The newly issued patent claims composition of matter of innate defense regulator (IDR) analogs, expanding patent protection around the Company’s lead IDR, dusquetide. Similar claims have been previously allowed in the US and are being pursued in other worldwide jurisdictions. To view this press release, please click here.
- On December 5, 2018, the Company announced the publication of a review article discussing the therapeutic applications of its innate immune modulator technology, including dusquetide (the active ingredient in SGX942), its lead clinical IDR. The article entitled, “Targeting Innate Immunity to Treat Disease: Potential Therapeutic Applications”, was published in the journal Drug Target Review online. To view this press release, please click here.

Financial Results – Year Ended December 31, 2018

Soligenix’s revenues for the year ended December 31, 2018 were $5.2 million as compared to $5.4 million for the prior year. Revenues included payments on a contract in support of RiVax®, in addition to the grants received to support the development of SGX301 for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer, as well as the subaward from the Ebola collaboration with the University of Hawai’i at Mānoa.

Soligenix’s basic net loss was $8.9 million, or ($0.68) per share for the year ended December 31, 2018, as compared to $7.1 million for the prior year, or ($1.16) per share.

Research and development expenses were $6.8 million as compared to $5.5 million for the years ended December 31, 2018 and 2017, respectively. The increase is primarily related to expenditures incurred in the expansion of the Phase 3 clinical trial of SGX942 as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $3.0 million as compared to $3.2 million for the years ended December 31, 2017 and 2016, respectively. This decrease was primarily a result of a decrease in professional fees and employee compensation expenses.

As of December 31, 2018, the Company’s cash position was approximately $9.0 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 BioTherapeutics business segment is developing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of 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 Vaccines/BioDefense 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. 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) 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.

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. 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 timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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.
