Soligenix Investor Relations

Soligenix Announces Recent Accomplishments And Year-End 2017 Financial Results

PRINCETON, NJ – March 15, 2018 – 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, 2017.

Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix stated, "In the third quarter of 2017, we initiated a 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 are actively enrolling patients in this study and expect final results in the second half of 2019. We also continue to actively enroll patients in our pivotal Phase 3 study in cutaneous T-cell lymphoma (CTCL) with SGX301 (synthetic hypericin), for which we expect results in the first half of 2019."

Dr. Schaber continued, "Throughout 2017, we were awarded in excess of $8.6 million in non-dilutive funding from various government sources across our entire biodefense and biotherapeutics pipeline in order to advance multiple development programs, which support we greatly appreciate. Our combined revenues from both our business segments were $5.4 million through our government contracts and grants as we continued to advance the development of our heat stable ricin vaccine, RiVax®, and our therapeutics, SGX301 and SGX942."

Soligenix Recent Accomplishments:

- On January 25, 2018, the Company issued an update letter from Dr. Schaber. This letter summarized progress and accomplishments during 2017 as well as provided further guidance on the development programs for 2018.
- On January 2, 2018, the Company announced that the United States (US) Patent and Trademark Office had granted the patent titled "Novel Peptides and Analogs for Use in the Treatment of Oral Mucositis." The newly issued patent claims therapeutic use of dusquetide (active ingredient in SGX942) and related innate defense regulator analogs, and adds to composition of matter claims for dusquetide and related analogs that have been granted in the US and worldwide. Dusquetide previously demonstrated positive results in a Phase 2 oral mucositis clinical trial and a pivotal Phase 3 study was initiated in 2017.
- On December 21, 2017, the Company announced that biomarkers for its ricin toxin vaccine (RiVax®) testing had been successfully identified, facilitating potential approval under the FDA "Animal Rule". The FDA Animal Rule is applied to products where testing in clinical trials would be unethical. In the case of a ricin toxin vaccine, clinical efficacy testing of the vaccine is unethical since exposing unvaccinated humans (i.e., placebo-control group) to ricin toxin would be fatal. The Animal Rule combines safety studies in humans and efficacy testing in animals, typically non-human primates, to facilitate approval and is generally associated with the approval of medical countermeasures for biodefense purposes. Key to the application of the Animal Rule is the requirement to establish a correlation between the response observed in clinical trials in healthy volunteers with the response demonstrated in animal efficacy studies. Identification of a biomarker to facilitate demonstrating the correlation between animal and human studies is a significant accomplishment in the RiVax® development program.
- On November 30, 2017, the Company announced that it had received preliminary approval for a tax credit from the New Jersey Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program. As a result, the Company transferred this credit and received approximately $417,000 in net proceeds in January 2018.

Financial Results – Year Ended December 31, 2017

Soligenix's revenues for the year ended December 31, 2017 were $5.4 million as compared to $10.4 million for the prior year. Revenues included contracts in support of OrbeShield® (oral beclomethasone 17,21-dipropionate) development for the treatment of gastrointestinal acute radiation syndrome and 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.

Soligenix's basic net loss was $7.1 million, or ($1.16) per share, as compared to $3.2 million for the prior year, or ($0.93) per share, on a split adjusted basis. Included in the net loss for the year ended December 31, 2016 is non-cash income of $1.5 million. This non-cash item reflects the change in fair value of the liability related to warrants issued in the Company's June 25, 2013 registered public offering and was included in total other income of $1.9 million.

Research and development expenses were $5.5 million as compared to $4.3 million for the years ended December 31, 2017 and 2016, respectively. The increase is primarily related to expenditures incurred in the preparation and initiation of the Phase 3 clinical trial of SGX942 as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $3.2 million as compared to $3.4 million for the years ended December 31, 2017 and 2016, respectively. This decrease was primarily a result of a decrease in professional fees.

As of December 31, 2017, the Company's cash position was $7.8 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, OrbeShield®, our GI acute radiation syndrome therapeutic 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 atwww.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 US 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 US 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. 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®. 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.
