SOLIGENIX, INC.
Form 8-K
December 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of

The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): December 8, 2016

Commission File No. 000-16929

Soligenix, Inc.

(Exact name of small business issuer as specified in its charter)

DELAWARE	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

29 Emmons Drive,

Suite C-10

Princeton, NJ **08540**
(Address of principal executive offices) (Zip Code)

(609) 538-8200

(Issuer's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On December 8, 2016, Soligenix, Inc. (the "Company") issued a press release announcing that it will be hosting an Investor Webcast Event Friday, December 16, 2016, from 8:30-9:30 am ET on the origins of Innate Defense Regulators as a new drug class, as well as a review of oral mucositis and the recently announced and published Phase 2 clinical data for SGX942 (dusquetide) in the treatment of oral mucositis ("OM") in head and neck cancer patients. The webcast may include forward-looking information. A copy of the press release is attached hereto as Exhibit 99.1.

Webcast Instructions

The live webcast event can be accessed at: https://engage.vevent.com/rt/soligenixinc~121616 (please copy and paste URL into web browser), with replay of the event to be made accessible on the Company's corporate website, www.soligenix.com. Alternatively, audio can be accessed by dialing Toll-Free 866-563-6458, Conference ID: 33796918.

Pursuant to general instruction B.2 to Form 8-K, the information furnished pursuant to this Item 7.01, including Exhibit 99.2, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01, including Exhibit 99.2, shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

Item 8.01 Other Events.

Also on December 8, 2016, the Company issued a press release announcing the long-term follow-up data from its Phase 2 clinical trial with SGX942 (dusquetide), a first-in-class Innate Defense Regulator, in the treatment of OM in head and neck cancer patients undergoing chemoradiation therapy ("CRT"). As described in further detail in the press release, the additional 12-month safety data remains consistent with the preliminary positive safety and efficacy findings from the Phase 2 study and provides further support for advancing SGX942 into a pivotal Phase 2b/3 clinical trial. Following the positive results announced in December 2015, in which SGX942 at a dose of 1.5 mg/kg was attributed with successfully reducing the median duration of severe OM by 50% in all patients and by 67% in patients at highest risk of developing severe OM, the Company announced that long-term follow-up visits conducted throughout 2016 further demonstrated that SGX942 was safe, well-tolerated, and did not interfere with CRT as demonstrated by improved survival and tumor resolution at one and 12 months. A copy of the press release is attached hereto as Exhibit 99.2.

Note about forward-looking statements. Certain statements in this report, other than purely historical information, including expectations about future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment, continued pursuit of partnership opportunities to support ongoing SGX942 clinical development, SGX942's potential as an effective treatment in OM and expected long-term safety and tolerability in a sick patient population, the expected submission for future presentation and publication of the long-term (12 month) follow-up data from the trial, and the assumptions upon which those statements are based, are "forward-looking statements." These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," "hope," "goal," "suggest," "potential," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. The Company cannot provide any assurance 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. The Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Soligenix, Inc. on December 8, 2016.
99.2	Press release issued by Soligenix, Inc. on December 8, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Soligenix, Inc.

December 8, 2016 By: **/s/ Christopher J. Schaber**
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)