SOLIGENIX, INC.
Form 424B3
September 16, 2011

Prospectus Supplement dated September 15, 2011

Filed Pursuant to Rule 424(b)(3)
File No. 333-167792

SOLIGENIX, INC.

This prospectus supplement supplements:

> the prospectus dated April 22, 2011 relating to the offer and sale by the selling stockholders identified in the prospectus of up to 31,458,638 shares of our common stock.

This prospectus supplement contains the Form 8-K that we filed with the Securities and Exchange Commission on September 15, 2011. This prospectus supplement should be read in conjunction with, and may not be utilized without, the relevant prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement is qualified by reference to the relevant prospectus except to the extent that the information in this prospectus supplement updates and supersedes the information contained in such prospectus, including any supplements or amendments thereto.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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): September 15, 2011

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):

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

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

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

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

Item 8.01 Other Events.

Pursuant to a pre-specified interim analysis for safety and futility for Soligenix, Inc.'s confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD"), the Data Safety Monitoring Board (the "DSMB") on September 14, 2011 reported their recommendation to Soligenix. The DSMB recommended that the study be stopped as it is highly unlikely to achieve the predetermined primary objective of efficacy based on the interim results. No safety concerns were raised. As a result of the DSMB's recommendation, patient enrollment in the study will stop and the data will be analyzed.

Item 9.01.Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Soligenix, Inc. on September 15, 2011.

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.

September 15, 2011 By: /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Soligenix Announces Results of Recent Data Safety Monitoring Board Review for Phase 3 orBec® Study in Acute GI GVHD

Soligenix to Host Investor Conference Call Today at 9AM EDT

Princeton, NJ – September 15, 2011 – Soligenix, Inc. (OTCBB: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company, announced that an independent Data Safety Monitoring Board (DSMB) recently completed a pre-specified interim analysis for safety and futility for Soligenix's confirmatory Phase 3 clinical trial of orBec® an oral formulation of beclomethasone dipropionate (BDP) in acute gastrointestinal Graft-versus-Host disease (GI GVHD).

The DSMB recommended that the study be stopped as it is highly unlikely to achieve the predetermined primary objective of efficacy based on the interim results. No safety concerns were raised. As a result of the DSMB's recommendation, patient enrollment in the study will stop and the data will be analyzed.

"We are obviously disappointed with the outcome of the DSMB's review," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Over the coming weeks, we will be analyzing the data. At this point, we do not know why the primary efficacy endpoint was not demonstrated by orBec®, as two prior studies with very similar designs demonstrated robust efficacy and clinically relevant results in essentially the same patient population. It is not possible at this exact time to determine what explains this unexpected outcome. One of a number of possibilities that will be investigated is that these results may be due to changes in the overall treatment practices of the allogeneic stem cell transplantation patient population that may have had an impact on the treatment effect of orBec® since the previous Phase 3 study was concluded in 2004. If there is any clarity gained from further analysis of the dataset, especially with respect to specific subsets of patients that may benefit from orBec® therapy, then we will certainly communicate our findings."

Dr. Schaber continued, "With approximately $7.4 million of cash, we can continue to evaluate other clinical applications for oral BDP in the areas of radiation enteritis, radiation injury, and Crohn's disease. With continued additional funding under our $9.4 million NIH grant, we can also continue to pursue development of our heat stabilization technology for subunit vaccines including application to RiVaxTM, our vaccine against ricin toxin. Additionally, we will be instituting cost containment measures as we evaluate our strategic options, including whether to further pursue the applications of orBec® in the GVHD treatment and prevention space in light of the results of the recent Phase 3 clinical trial."

The Company will host a webcast and conference call today at 9AM EDT to review the DSMB recommendation. To participate in the conference call, please dial the following toll free number: (877) 407-3974. International callers may dial: (201) 689-8886. After prepared remarks by management, a question-and-answer session will follow. Listeners may also participate via webcast approximately 10 minutes prior to the start of the call by visiting the Soligenix website investor relations page at http://www.soligenix.com/invest_sec.shtml. The webcast is best viewed using Internet Explorer.

About orBec®

orBec®, oral beclomethasone dipropionate (oral BDP), was recently the subject of a confirmatory Phase 3 clinical trial in the treatment of acute GI GVHD which was stopped for futility. This Phase 3 trial, also referred to as the SUPPORTS protocol (Sparing Unnecessary Prednisone Phase 3 orBec® Randomized Treatment Study), enrolled 140 patients and was designed to confirm the clinically meaningful endpoints observed in previous Phase 2 and Phase 3 clinical studies. The primary endpoint was the treatment failure rate at Study Day 80. Analysis of this endpoint was positive as a secondary endpoint (p-value 0.005) in the Company's previous Phase 3 study as a clinically significant outcome following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment). The SUPPORTS trial was conducted at major transplant centers throughout the US, Europe, and Australia. The trial was the subject of a Special Protocol Assessment (SPA) agreement that the Company reached with the US Food and Drug Administration (FDA). It was determined in a pre-specified interim analysis that this study was unlikely to achieve the primary efficacy objective.

orBec® was the subject of two prior randomized, double-blind, placebo-controlled clinical trials in acute GI GVHD. The first study was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center, which demonstrated statistical significance in its primary endpoint of controlling GI GVHD (p-value 0.02). The second study was a 129-patient pivotal Phase 3 multi-center clinical trial conducted at 16 leading bone marrow/stem cell transplant centers in the US and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time to treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). At one year post-randomization in the Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p-value 0.04).

orBec® is formulated for oral administration as a single product consisting of two tablets; one tablet is intended to release BDP in the proximal portions of the GI tract, and the other tablet is intended to release BDP in the distal portions of the GI tract. Oral BDP may also have application in treating other GI disorders characterized by severe inflammation.

About Soligenix, Inc.

Soligenix is a late-stage biopharmaceutical company developing products to treat life-threatening side effects of cancer treatments and serious gastrointestinal diseases, and vaccines for certain bioterrorism agents. Soligenix's lead product, orBec® (oral beclomethasone dipropionate), is a potent, locally acting corticosteroid that has been initially developed for the treatment of acute gastrointestinal Graft-versus-Host disease (GI GVHD), a common and potentially life-threatening complication of hematopoietic cell transplantation. Soligenix is also conducting a National Cancer Institute (NCI)-supported Phase 1/2 clinical trial of SGX201 in the prevention of acute radiation enteritis. Additionally, Soligenix has a Lipid Polymer Micelle (LPM™) drug delivery technology for the oral delivery of leuprolide for the treatment of prostate cancer and endometriosis.

Through its Biodefense Division, Soligenix is developing countermeasures pursuant to the Project BioShield Act of 2004. Soligenix's lead biodefense product in development is a recombinant subunit vaccine called RiVax™, which is designed to protect against the lethal effects of exposure to ricin toxin. RiVax™ has been shown to be well tolerated and immunogenic in a Phase 1 clinical trial in normal volunteers. RiVax™ is currently the subject of a $9.4 million NIAID grant supporting development of new heat stable vaccines. Soligenix is also developing SGX202 for the treatment of radiation injury and has recently released positive preliminary preclinical results in a canine gastrointestinal acute radiation syndrome model.

For further information regarding Soligenix, Inc., please visit the Company's website at www.soligenix.com.

This press release contains forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities. Statements that are not historical facts, such as "anticipates," "believes," "intends," 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 or commercialize products based on its technology, including orBec®, SGX201, RiVax™, and LPMTM, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats, manufacturing and conducting preclinical and clinical trials of vaccines, and obtaining regulatory approvals, that its cash expenditures will not exceed projected levels, 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 grants and awards, maintain its existing grants which are subject to performance, enter into any biodefense procurement contracts with the US Government or other countries, that the US Congress may not pass any legislation that would provide additional funding for the Project BioShield program, that it will be able to patent, register or protect its technology from challenge and products from competition or maintain or expand its license agreements with its current licensors, or that its business strategy will be successful. Important factors which may affect the future use of orBec® for gastrointestinal GVHD include the DSMB's recent determination disclosed in this press release recommending that Soligenix stop its confirmatory Phase 3 clinical trial of orBec® in acute GI GVHD and the risk that: the FDA will require that Soligenix conduct additional clinical trials to demonstrate the safety and efficacy of orBec® which will take a significant amount of time and money to complete and positive results leading to regulatory approval cannot be assumed; Soligenix is dependent on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of its products; orBec® may not gain market acceptance if it is eventually approved by the FDA; and others may develop technologies or products superior to orBec®. Factors affecting the development and use of SGX201 and LPMTM are similar to those affecting orBec®. These and other 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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