

SOLIGENIX, INC.

Form S-1

December 17, 2013

As filed with the Securities and Exchange Commission on December 17, 2013.

Registration No. _____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

41-1505029
(I.R.S. Employer
Identification No.)

Soligenix, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

(Address, including zip code, and telephone number, including area code,
of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
Soligenix, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

with copies to:

Leslie J. Croland, Esq.
Duane Morris LLP
Suite 3400
200 South Biscayne Boulevard
Miami, Florida 33131-2318
(305) 960-2200

Edgar Filing: SOLIGENIX, INC. - Form S-1

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee (2)
Common Stock, \$0.001 par value per share (3)	3,905,440	\$1.935	\$7,557,027	\$974

- (1) The shares of our common stock being registered hereunder are being registered for sale by the selling stockholder, as defined in the accompanying prospectus.
- (2) Estimated solely for purposes of calculating the registration fee according to Rule 457(c) under the Securities Act of 1933, as amended, on the basis of the average of the bid and asked prices of the Registrant's common stock reported on the OTCQB on December 12, 2013.
- (3) This registration statement also covers the preferred stock purchase rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between the Registrant and American Stock Transfer & Trust Company, as Rights Agent, which are presently attached to and trade with the Registrant's common stock.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholder not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED DECEMBER 17,
2013

SOLIGENIX, INC.

3,905,440 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale of up to 3,905,440 shares of our common stock by Lincoln Park Capital Fund, LLC (“Lincoln Park”). Lincoln Park is sometimes referred to in this prospectus as the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to the purchase agreement dated November 18, 2013 that we entered into with Lincoln Park, which we refer to in this prospectus as the “Purchase Agreement.” Please refer to the section of this prospectus entitled “The Lincoln Park Transaction” for a description of the Purchase Agreement and the section entitled “Selling Stockholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

Soligenix, Inc. is not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder. References in this prospectus to the “Company,” “we,” “our,” and “us” refer to Soligenix Inc.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution.”

Our common stock is currently quoted on the OTCQB market under the symbol “SNGX”. On December 12, 2013, the last quoted sale price of our common stock as reported on the OTCQB was \$1.96 per share.

Investing in our securities involves significant risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2013

Table of Contents

<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	ii
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	5
<u>USE OF PROCEEDS</u>	15
<u>DIVIDENDS</u>	15
<u>DILUTION</u>	16
<u>BUSINESS</u>	17
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	35
<u>MANAGEMENT</u>	41
<u>EXECUTIVE COMPENSATION</u>	45
<u>SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT</u>	49
<u>TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS</u>	51
<u>THE LINCOLN PARK TRANSACTION</u>	52
<u>SELLING STOCKHOLDER</u>	55
<u>PLAN OF DISTRIBUTION</u>	57
<u>DESCRIPTION OF SECURITIES</u>	58
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	61
<u>DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES</u>	62
<u>EXPERTS</u>	63
<u>LEGAL MATTERS</u>	63
<u>AVAILABLE INFORMATION</u>	63
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information.

We have not authorized the placement agent or any underwriters, brokers or dealers to make an offer of the units in any jurisdiction where the offer is not permitted.

You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of this prospectus.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements. These forward-looking statements are often identified by words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "continue," "plan," "potential" and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

our dependence on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;

the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our proposed products, including: (i) the timing, status and results of our or our commercial partners' filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies, including regulatory review thereof and (iii) the heavily regulated industry in which we operate our business generally;

significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;

uncertainty as to whether our technologies will be safe and effective to support regulatory approvals;

our ability to obtain future financing or funds when needed, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;

that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;

our ability to obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;

our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;

our ability to patent, register and protect our technology from challenge and our products from competition;

maintenance or expansion of our license agreements with our current licensors;

the protection and control afforded by our patents or other intellectual property, and any interest in patents or other intellectual property that we license, or our or our partners' ability to enforce our rights under such owned or licensed patents or other intellectual property;

changes in healthcare regulation;

changes in the needs of biodefense procurement agencies;

maintenance and progression of our business strategy;

Table of Contents

the possibility that our products under development may not gain market acceptance;

our expectations about the potential market sizes and market participation potential for our approved or proposed products;

our expected revenues (including sales, milestone payments and royalty revenues) from our products or product candidates and any related commercial agreements of ours;

the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise; and

competition existing today or that may arise in the future, including the possibility that others may develop technologies or products superior to our products.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the risk factors and the financial statements. References in this prospectus to “we,” “us,” “our,” and “Soligenix” refer to Soligenix, Inc. You should read both this prospectus together with additional information described below under the heading “Available Information.”

About Our Company

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing 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), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our GI acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. With the recently awarded government contracts from the Biomedical Advanced Research and Development Authority (“BARDA”) and the National Institute of Allergy and Infectious Diseases (“NIAID”), we will attempt to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we entered into a global and exclusive channel collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline of our business strategy follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis and treatment of chronic graft –versus host disease (“GI GVHD”);
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology known as ThermoVax™ to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
- Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
-

Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

· Acquire or in-license new clinical-stage compounds for development; and

· Explore other business development and acquisition strategies, an example of which is the recently announced collaboration with Intrexon.

Table of Contents

The following tables summarize the products that we are currently developing:

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, data pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 2/3 clinical trial planned for the first half of 2014, with data expected in the first half of 2015
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2014, with data expected in the second half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

Soligenix Product	Indication	Stage of Development
ThermoVax™	Thermostability of aluminum adjuvanted vaccines	Pre-clinical

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the second half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	Melioidosis	Pre-clinical

Corporate Information

We were incorporated in Delaware in 1987 under the name Immunotherapeutics Inc. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Table of Contents

The Offering

On November 18, 2013, we entered into the Purchase Agreement with Lincoln Park, pursuant to which we sold to Lincoln Park 285,714 shares of our common stock for \$600,000 and Lincoln Park has agreed to purchase from us up to an aggregate of \$10,600,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on November 18, 2013, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park, pursuant to which we have filed with the U.S. Securities and Exchange Commission (the “SEC”) the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the “Securities Act”), the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than (i) 285,714 shares of our common stock that we have already issued to Lincoln Park for a total purchase price of \$600,000 as an initial purchase under the Purchase Agreement (the “Initial Purchase”), and (ii) 97,656 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 75,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also increase the amount of our common stock to be purchased under certain circumstances to up to 100,000 shares but not exceeding \$750,000 per purchase plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than \$1.00 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. &#