

SOLIGENIX, INC.

Form POS AM

April 28, 2010

As filed with the Securities and Exchange Commission on April 28, 2010.

Registration No. 333-157322

---

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

---

POST-EFFECTIVE AMENDMENT NO. 1  
TO  
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.  
Edwards Angell Palmer & Dodge LLP  
One North Clematis Street, Suite 400  
West Palm Beach, Florida 33401-5552  
(561) 833-7700

---

Edgar Filing: SOLIGENIX, INC. - Form POS AM

Approximate date of commencement of proposed sale to the public: From time to time, at the discretion of the selling stockholders, after the effective date of this registration statement.

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: x

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. o

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. o

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. o

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)

\_\_\_\_\_

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 Stockholders may 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.

SUBJECT TO COMPLETION, DATED APRIL 28, 2010

PROSPECTUS

Soligenix, Inc.

44,491,610 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 44,491,610 shares of our common stock by the selling stockholders named in this prospectus in the section "Selling Stockholders," including their pledgees, assignees and successors-in-interest, whom we collectively refer to in this document as the "Selling Stockholders." We completed a private placement in which we issued to certain of the Selling Stockholders an aggregate of 20,914,035 shares of our common stock, together with warrants to purchase up to 914,035 shares of our common stock. We also issued 16,666,667 shares of our common stock to one of the Selling Stockholders in connection with the execution of a letter of intent. In addition, we issued 2,713,539 shares of our common stock to certain of the Selling Stockholders as compensation for services rendered to us, warrants to purchase up to 1,000,000 shares of our common stock for a finder's fee and warrants to purchase up to 1,450,000 shares of our common stock for services rendered. We may issue 833,334 shares of our common stock to one of the Selling Stockholders as payment for services to be rendered to us. The common stock offered by this prospectus shall be adjusted to cover any additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions. The prices at which the Selling Stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of any of the shares covered by this prospectus unless warrants are exercised. References in this prospectus to the "Company," "we," "our," and "us" refer to Soligenix, Inc.

Our common stock is quoted on the Over-the-Counter Bulletin Board ("OTCBB") under the symbol "SNGX." On April 27, 2010, the last quoted sale price for our common stock as reported on the OTCBB was \$0.29 per share.

Investing in our common stock involves certain risks. See "Risk Factors" beginning on page 4 for a discussion of these risks.

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.

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

The date of this prospectus is \_\_\_\_\_, 2010



## Table of Contents

Description	Page
	1
Forward-Looking Statements	2
Prospectus Summary	4
Risk Factors	13
Business	26
Management's Discussion and Analysis or Plan of Operation	32
Directors and Executive Officers	35
Executive Compensation	38
Security Ownership of Principal Stockholders and Management	40
Selling Stockholders	41
Use of Proceeds	42
Plan of Distribution	42
Description of Securities	44
Market for Common Equity and Related Stockholder Matters	45
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	46
Experts	46
Legal Matters	46
Index to Financial Statements	F-1

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

We have not authorized the Selling Stockholders to make an offer of these shares of common stock in any jurisdiction where the offer is not permitted.

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

## 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” and similar expressions. These statements include 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 ability to successfully complete the confirmatory Phase 3 clinical trial of orBec® for the treatment of gastrointestinal Graft-versus-Host disease;
- the possibility that orBec® may not show therapeutic effect or an acceptable safety profile in future clinical trials, or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval;
- 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;
- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to make certain that our cash expenditures do not exceed projected levels;
- our ability to obtain future financing or funds when needed;
- 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 successfully 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;
- changes in healthcare regulation;
- changes in the needs of biodefense procurement agencies;
- maintenance of a successful business strategy;
- the possibility that orBec® may not gain market acceptance; and
- 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.



## PROSPECTUS SUMMARY

## About Our Company

Soligenix, Inc., formerly known as DOR BioPharma, Inc., was incorporated in Delaware in 1987. We are a late-stage research and development biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatment and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and BioDefense. Our BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, including LPMTM Leuprolide. Our BioDefense business segment intends to convert its ricin toxin vaccine and radiation injury program from early stage development to advanced development and manufacturing.

Our business activities can be outlined as follows:

- complete the pivotal Phase 3 confirmatory clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”);
- identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) to commercialize orBec® in the U.S., Canada and Mexico;
  - conduct and complete a Phase 2 clinical trial of orBec® for the prevention of acute GVHD;
- evaluate and initiate additional clinical trials to explore the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal tract such as radiation enteritis, radiation injury and Crohn’s disease;
  - reinitiate development of our other biotherapeutics products, including LPMTM Leuprolide;
- continue to secure additional government funding for each of our BioDefense programs through grants, contracts and procurements;
- convert our biodefense vaccine programs from early stage development to advanced development and manufacturing with the potential to collaborate and/or partner with other companies in the biodefense area;
  - acquire or in-license new clinical-stage compounds for development; and
  - explore other business development and acquisition strategies.

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.

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

## BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
orBec®	Treatment of Acute GI GVHD	Pivotal Phase 3 confirmatory trial enrolling
orBec®	Prevention of Acute GI GVHD	Phase 2 trial enrolling
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial potentially to be initiated in 2010
SGX 201	Acute Radiation Enteritis	Phase 1/2 trial initiated
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Phase 1 trial potentially to be initiated in 2010



BioDefense Products

Target	Available Countermeasure	Soligenix Product
Ricin Toxin	No vaccine or antidote currently FDA approved	Injectable ricin vaccine Phase 1 clinical trial successfully completed Second Phase 1 trial enrolling
Radiation Injury	No vaccine or antidote currently FDA approved	SGX 202 (pre-clinical)

## The Offering

This prospectus relates to the offer and sale, from time to time, of up to 44,491,610 shares of our common stock by the Selling Stockholders. We are also registering for sale any additional shares of common stock which may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

The Selling Stockholders may sell these shares in the over-the-counter market or otherwise, at market prices prevailing at the time of sale or at negotiated prices. We will not receive any proceeds from the sale of shares by the Selling Stockholders. See "Plan of Distribution."

As of April 27, 2010, there were 186,972,036 shares outstanding, including 40,294,241 of the 44,491,610 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus represents approximately 23.81% of the total common stock outstanding as of April 27, 2010.

## RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Below are the significant risks and uncertainties of which we are aware. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this prospectus, including our financial statements and the related notes.

### Risks Related to our Industry

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts.

We have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2009, we had \$7.7 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next 18 months, we expect to be able to maintain the current level of our operations beyond the first quarter of 2011 and conduct the pivotal Phase 3 confirmatory clinical trial of orBec® for the treatment of acute GI GVHD.

We have sufficient funds through our existing biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”), to finance our biodefense projects. On September 21, 2009, we announced that we had received an NIAID grant for approximately \$9.4 million for the development of our biodefense programs. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 22% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs. We expect that our existing NIH biodefense grants will cover approximately \$600,000 of such fixed overhead costs over the next several years.

Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through December 31, 2009, we had expended approximately \$30.2 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least \$10 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from orBec®, our lead product candidate, or another one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

If we are unsuccessful in developing our products, our ability to generate revenues will be significantly impaired.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development,

pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

4

---

- we may not be able to maintain our current research and development schedules;
- we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;
  - we may encounter problems in clinical trials or Named Patient Access programs (“NPAP”); or
    - the technology or product may be found to be ineffective or unsafe.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any