

SOLIGENIX, INC.  
Form POS AM  
April 14, 2011

---

---

As filed with the Securities and Exchange Commission on April 14, 2011.

Registration No. 333-149239

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

---

POST-EFFECTIVE AMENDMENT  
NO. 3  
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  
525 Okeechobee Blvd., Suite 1600

Edgar Filing: SOLIGENIX, INC. - Form POS AM

West Palm Beach, Florida 33401

(561) 833-7700

---

---

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:

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)

---

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 14, 2011

PROSPECTUS

Soligenix, Inc.

26,563,613 Shares of Common Stock

This prospectus relates to the sale from time to time of up to 26,563,613 shares of our common stock by the selling stockholders named in this prospectus in the section "Selling Stockholders," whom we collectively refer to in this document as the "Selling Stockholders." 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. 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 11, 2011, the last quoted sale price for our common stock as reported on the OTCBB was \$0.20 per share.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under applicable state securities laws or that an exemption from registration is available.

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

One of the Selling Stockholders, Fusion Capital Fund II, LLC ("Fusion Capital"), is deemed an "underwriter" within the meaning of the Securities Act of 1933, as amended. The other Selling Stockholders may be deemed "underwriters" within the meaning of the Securities Act of 1933, as amended.

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 \_\_\_\_\_, 2011

## Table of Contents

<u>FORWARD-LOOKING STATEMENTS</u>	1
<u>PROSPECTUS SUMMARY</u>	2
<u>RISK FACTORS</u>	4
<u>BUSINESS</u>	13
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION</u>	27
<u>DIRECTORS AND EXECUTIVE OFFICERS</u>	34
<u>EXECUTIVE COMPENSATION</u>	37
<u>SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT</u>	41
<u>THE FUSION TRANSACTION</u>	43
<u>SELLING STOCKHOLDERS</u>	46
<u>USE OF PROCEEDS</u>	47
<u>PLAN OF DISTRIBUTION</u>	47
<u>DESCRIPTION OF SECURITIES</u>	49
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	51
<u>DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT</u>	52
<u>LIABILITIES</u>	
<u>EXPERTS</u>	52
<u>LEGAL MATTERS</u>	52
<u>AVAILABLE INFORMATION</u>	52
<u>INDEX TO FINANCIAL STATEMENTS</u>	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 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 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 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. 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 several 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, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”), will commercialize orBec® in North America once approved by the U.S. Food and Drug Administration (the “FDA”). Our BioDefense business segment intends to use RiVax™, our ricin toxin vaccine, to support development efforts in the area of our heat stabilization technology and SGX202, our radiation injury program, to convert from early stage development to advanced development and manufacturing with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

- complete the confirmatory Phase 3 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 to commercialize orBec® in the U.S., Canada and Mexico;
  - complete the Phase1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal (“GI”) tract such as prevention of acute GVHD, treatment of chronic GVHD, radiation injury, and Crohn’s disease;
- continue to secure additional government funding for each of our BioDefense programs through grants, contracts and/or procurements;
- use RiVax™ to support development efforts with our heat stabilization technology into the development of new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
  - 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; expected to complete in 2H 2011
orBec®	Prevention of Acute GI GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial potentially to be initiated in 2H 2011



SGX201

Acute Radiation Enteritis

Phase 1/2 trial enrolling;  
expected to complete in 1H 2011

LPM™ Leuprolide

Endometriosis and Prostate Cancer

Pre-clinical

2

---

## BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial enrollment complete; data expected in 1H 2011
SGX202	Radiation Injury	Pre-clinical

## The Offering

This prospectus relates to the offer and sale from time to time of up to 26,563,613 shares of our common stock by the Selling Stockholders, 881,112 shares of which were issued to seven of the Selling Stockholders in a private placement on February 14, 2008 and 354,722 shares of which were issued to two of the Selling Stockholders as compensation for consulting services rendered.

Fusion Capital, one of the Selling Stockholders under this prospectus, is offering for sale up to 25,327,778 shares of our common stock. Fusion Capital is not an affiliate of, and has no relation to, any of the other Selling Stockholders named herein. On February 14, 2008, we entered into a common stock purchase agreement with Fusion Capital. Under the agreement, as amended, Fusion Capital is obligated, under certain conditions, to purchase shares from us in an aggregate amount of \$8.5 million from time to time over a 43-month period, ending on October 31, 2011. We have sold 5,717,297 shares of common stock to Fusion Capital (together with a four-year warrant to purchase 1,388,889 shares of our common stock and a five-year warrant to purchase 100,000 shares of our common stock that are not part of this offering) under the agreement for total proceeds of approximately \$957,500. Under the terms of the common stock purchase agreement, as amended, Fusion Capital received a commitment fee consisting of 1,275,000 shares of our common stock upon the execution of the agreement. We have issued 143,625 additional shares as a pro rata commitment fee in connection with the purchase by Fusion Capital of the approximately \$957,500 of our common stock. We also will issue to Fusion Capital an additional 1,131,375 shares as a commitment fee pro rata as we receive the approximately \$7,542,500 of future funding. All 2,550,000 shares issued or to be issued to Fusion Capital as a commitment fee are being included in the offering pursuant to this prospectus. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement.

As of April 11, 2011, there were 217,666,590 shares outstanding (200,797,998 shares held by non-affiliates), excluding the 17,060,481 shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of such 17,060,481 shares that may be sold to Fusion Capital and are offered hereby were issued and outstanding as of the date hereof, the 17,060,481 shares would represent approximately 7.8% of the total common stock outstanding, or approximately 8.5% of the non-affiliates shares outstanding, as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement.

We do not have the right to commence any additional sales of our shares to Fusion Capital until the Securities and Exchange Commission ("SEC") has declared effective the registration statement of which this prospectus is a part. After the SEC has declared effective such registration statement, generally we have the right but not the obligation from time to time to sell our shares to Fusion Capital in amounts between \$80,000 and \$1.0 million depending on certain conditions. We have the right to control the timing and amount of any sales of our shares to Fusion Capital. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale. Fusion Capital shall neither have the right nor the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below \$0.10. The agreement may be terminated by us at any time at our discretion without any cost to us.



## 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 Business

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, 2010, we had \$7.5 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years, we expect to be able to maintain the current level of our operations into the second quarter of 2012 and complete 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 for the next several years. In September 2009, we received a 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 March 2011, we have expended approximately \$37.8 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
  - 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 other technology we develop, even if it is shown to be effective, if:

- it is not economical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
  - the product is not eligible for third-party reimbursement from government or private insurers;
  - others hold proprietary rights that preclude us from commercializing the product;
    - we are not able to manufacture the product reliably;
    - others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

We received a “not approvable letter” from the FDA for our lead product candidate orBec®.

Our business is subject to very stringent U.S., federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

On October 18, 2007, we received a “not approvable letter” from the FDA for our lead product candidate, orBec®, for the treatment of acute GI GVHD. The letter stated that the FDA requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an “End of Review Conference” with the FDA to further understand the letter and gain clarity regarding the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipated working quickly with the FDA to finalize the design of the confirmatory trial under the Agency’s “Special Protocol Assessment” process; and (3) the FDA would be agreeable to reviewing a plan for a Treatment Investigational New Drug (“Treatment IND”) as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study.

On January 5, 2009, we reached an agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA’s Special Protocol Assessment procedure. The confirmatory Phase 3 clinical trial for the treatment of acute GI GVHD has been initiated and is expected to complete in the second half of 2011.

Although we intend to obtain FDA approval for orBec®, there can be no assurances that the FDA will ever approve orBec® for market launch. Furthermore, the FDA may mandate additional testing or data, which may take additional time and expense to provide.



Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccines we are developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government's biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing.

We will be dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our successful receipt of government funding is also dependant on our ability to adhere to the terms and provisions of the original grant documents and other regulations.





If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or are anticipating having internal manufacturing capabilities.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

The manufacture of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice (“cGMP”) or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA’s cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. Although we have a collaboration agreement with Sigma-Tau for the sales and marketing of orBec® in North America, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

Federal and/or state health care reform initiatives could negatively affect our business.

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations, such as orBec® for the treatment of acute and chronic GI GVHD and prevention of GVHD.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that are currently separately billed. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We cannot speculate on the potential sales impact to orBec® based on the new rule.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from the University of Texas Southwestern Medical Center, the University of Texas Medical Branch at Galveston, the University of Colorado, and George B. McDonald, MD for the rights to

commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America or enter into an agreement for the commercialization of orBec® with another company. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of \$5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may not be able to compete successfully with our competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The Patent and Trademark Office may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We currently have only 15 employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We will not be successful if our management team cannot effectively manage and operate our business. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

During recent months, there has been substantial volatility and a decline in financial markets due at least in part to the deteriorating global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by the current economic crisis. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through

borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.



## Risks Related to our Common Stock

Our common stock price is highly volatile.

The market price of our common stock, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so in the future due to a wide variety of factors, including:

- announcements by us or others of results of pre-clinical testing and clinical trials;
- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
  - our quarterly operating results and performance;
  - developments or disputes concerning patents or other proprietary rights;
    - acquisitions;
    - litigation and government proceedings;
      - adverse legislation;
      - changes in government regulations;
        - our available working capital;
    - economic and other external factors; and
      - general market conditions.

Since January 1, 2010, our stock price has fluctuated between a high of \$0.30 per share to a low of \$0.15 per share. As of April 11, 2011, our common stock traded at \$0.20 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock by the Company, and subsequent sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

Our common stock trades on the Over-the-Counter Bulletin Board.

Our common stock trades on the OTCBB securities market under the symbol “SNGX.” The OTCBB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies. On the OTCBB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCBB securities include national, regional, and foreign equity issues. Companies traded on the OTCBB must be current in their reports filed with the Securities and Exchange Commission (the “SEC”) and other regulatory authorities.

If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Our common stock is subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share, other than securities registered on certain national securities exchanges provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s written agreement to the

transaction. As a result of these requirements, our common stock could be priced at a lower price and our stockholders could find it more difficult to sell their shares.

Shareholders may suffer substantial dilution related to issued stock warrants and options.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 54,076,373 shares of our common stock at a current weighted average exercise price of approximately \$0.22; and
- options to purchase approximately 26,161,039 shares of our common stock at a current weighted average exercise price of approximately \$0.24.

To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

On February 14, 2008, we entered into an \$8,500,000 common stock purchase agreement with Fusion Capital. The Fusion Capital facility, as amended, allows us to require Fusion Capital to purchase between \$80,000 and \$1.0 million, depending on certain conditions, of our common stock up to an aggregate of \$8.5 million over approximately a 43-month period, ending on October 31, 2011. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four-year warrant to purchase 1,388,889 shares of common stock at \$0.22 per share, for an aggregate price of \$500,000. From February 14, 2008 through April 11, 2011, we have issued an additional 2,864,520 shares of common stock, a five-year warrant to purchase 100,000 shares of common stock at \$0.303 per share and received an additional \$392,500 in proceeds from the Fusion Capital facility.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 25,327,778 shares registered by us for sale by Fusion Capital are freely tradable. It is anticipated that those shares will be sold over a period of up to 6 months from April 14, 2011, the date of this prospectus covering the Fusion Capital shares. Depending upon market liquidity at the time, a sale of these shares under the registration statement at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the approximately 18 million shares of common stock not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

The common stock purchase agreement with Fusion Capital also may be terminated in the event of a default under the agreement. In addition, we cannot require Fusion Capital to purchase any shares of our common stock if the purchase price is less than \$0.10 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. The closing price of our common stock on April 11, 2011 was \$0.20 per share.

Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

## BUSINESS

### Our Business Overview

Soligenix, 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 several 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, while our collaboration partner, Sigma-Tau, will commercialize orBec® in North America once approved by the FDA. Our BioDefense business segment intends to use RiVax™, our ricin toxin vaccine, to support development efforts in the area of our heat stabilization technology and SGX202, our radiation injury program, to convert from early stage development to advanced development and manufacturing with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute 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 to commercialize orBec® in the U.S., Canada and Mexico;
  - complete the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute GVHD, treatment of chronic GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioDefense programs through grants, contracts and/or procurements;
- use RiVax™ to support development efforts with our heat stabilization technology into the development of new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
  - 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.

## Our Products in Development

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; expected to complete in 2H 2011
orBec®	Prevention of Acute GI GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial potentially to be initiated in 2H 2011
SGX201	Acute Radiation Enteritis	Phase 1/2 trial enrolling; expected to complete in 1H 2011
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

## BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial enrollment complete; data expected in 1H 2011
SGX202	Radiation Injury	Pre-clinical

## BioTherapeutics Overview

## orBec® and oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of acute GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active ingredient in orBec® is beclomethasone dipropionate (“BDP”), a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970’s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract.

Based on data from the prior Phase 3 study of orBec®, the current confirmatory Phase 3 study is a highly powered, double-blind, randomized, placebo-controlled, multi-center trial and will seek to enroll an estimated 166 patients. This trial is supported in part by a \$1.2 million FDA Orphan Products grant. The primary endpoint is the treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-value 0.005) in the previous Phase 3 study as a key measure of durability following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment).

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® would benefit from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, as well as an orphan drug designation in the U.S for the treatment of chronic GI GVHD. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S and Europe, respectively.

Historical Background

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support the ability of orBec® to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center (“FHCRC”) in Seattle, Washington. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the U.S. 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). Within one year after randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died (46% reduction in mortality, p-value 0.04).

In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients at Day 30 (the end of treatment) had a durable GVHD treatment response as measured by whether or not they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the orBec® and placebo groups, respectively (p-value 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) vs. 5 of 29 (17%) in the orBec® and placebo groups, respectively (p-value 0.007).

Based on the data from the above referenced Phase 2 and Phase 3 studies, on September 21, 2006, we filed a new drug application (“NDA”) for our lead product orBec® with the FDA for the treatment of acute GI GVHD. On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of this letter.

In December 2008, we reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating orBec® for the treatment of acute GI GVHD under the FDA’s Special Protocol Assessment (“SPA”) procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the FDA can only change a SPA for very limited reasons. Further, in June 2009, we received Protocol Assistance feedback from the European Medicines Agency (“EMA”) on the design of the Phase 3 clinical protocol for orBec®. The EMA agreed that should the new confirmatory Phase 3 study produce positive results, the data would be sufficient to support a marketing authorization in all 27 European Union member states. The confirmatory Phase 3 trial is enrolling patients and is expected to complete in the second half of 2011.

If the confirmatory Phase 3 trial is successful, we will file a complete response to the FDA action letter. This response is expected to be designated a class II response with a corresponding FDA review time frame of 6 months.

Mortality Results

	Phase 3 Trial		Phase 2 Trial	
	orBec®	Placebo	orBec®	Placebo



Edgar Filing: SOLIGENIX, INC. - Form POS AM

Number of patients randomized	62	67	31	29
Number (%) who died	5 (8%)	16 (24%)	3 (10%)	6 (21%)
Hazard ratio (95% confidence interval)	0.33 (0.12, 0.89)		0.47 (0.12, 1.87)	
Death with infection*	3 (5%)	9 (13%)	2 (6%)	5 (17%)
Death with relapse*	3 (5%)	9 (13%)	1 (3%)	4 (14%)

\*Some patients died with both infection and relapse of their underlying malignancy.

Among the data from the Phase 3 clinical study of orBec® reported in the January 2007 issue of *Blood*, the peer-reviewed Journal of the American Society of Hematology, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, “the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p-value 0.03, Wald chi-square test).” The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of mortality 200 days post-transplantation.

In this Phase 3 study, orBec® showed continued survival benefit when compared to placebo one year after randomization. Overall, 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). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p-value 0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to orBec® compared with placebo (p-value 0.03).

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significant. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

#### Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo. This effect was far less pronounced than those seen in patients on high dose prednisone.

#### Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50% of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.



On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec® in the U.S., Canada and Mexico (the “Territory”). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of \$1 million was made in connection with the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD in September 2009. Total additional milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to \$9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities. In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for \$0.18 per share, for an aggregate price of \$4,500,000. The purchase price is equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,666,667 common shares at \$0.09 per share (the market price at the time) for proceeds of \$1,500,000 in exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009.

Additionally, orBec® is sold through Named Patient Access Programs (“NPAPs”) in South Korea, Latin America, Canada, Australia, South Africa, New Zealand and the ASEAN countries. The NPAPs are compassionate use drug supply programs under which medical practitioners can legally supply investigational drugs to their eligible patients. Under this program, drugs can be administered to patients who are suffering from serious illnesses prior to the drug being approved by the various regional regulatory authorities. The activity under NPAP programs is currently minimal.

We believe the potential worldwide market for orBec® to be approximately \$400 million for all GVHD applications, namely, treatment of acute and chronic GI GVHD and prevention of acute GVHD.

#### About GVHD

GVHD occurs in patients following allogeneic stem cell transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. will develop some form of acute GI GVHD.

GI GVHD is one of the most common causes for the failure of stem cell transplantation. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat acute GI GVHD. Currently used systemic immunosuppressives utilized to control GI GVHD substantially inhibit the highly desirable Graft-versus-Leukemia (“GVL”) effect of stem cell transplantations, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

#### About Allogeneic Hematopoietic Cell Transplantation

Allogeneic hematopoietic cell transplantation (“HCT”) is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HCT procedure, hematopoietic stem cells are harvested from the

blood or bone marrow of a closely matched relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or intense immunosuppressive conditioning therapy. The curative potential of allogeneic HCT is now partly attributed to the GVL or Graft-versus-Tumor effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, the establishment of unrelated donor programs, the use of cord blood as a source of hematopoietic stem cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of high-dose chemotherapy. Based on the latest statistics available, it is estimated that there are more than 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the current annual rate of increase in these procedures are as high as 20%. High rates of morbidity and mortality occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplantation has also been studied as a curative therapy for several genetic disorders, including immunodeficiency syndromes, inborn errors of metabolism, and sickle cell disease. The primary toxicity of allogeneic HCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

#### Future Potential Indications of orBec® and oral BDP

Based on its pharmacological characteristics, orBec® may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following HCT, as well as GVHD which also occurs following organ allograft transplantation. We also have an issued U.S. patent 7,704,985 claiming the use of oral BDP to treat IBS, a painful gastrointestinal condition that affects approximately 15% of the population in the industrialized world. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We recently completed a Phase 2 trial of orBec® in the prevention of acute GVHD and have announced preliminary results from the study. We are targeting to begin a Phase 2 clinical trial in chronic GI GVHD in the second half of 2011, pending further funding. In addition, we are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Crohn's Disease, Lymphocytic Colitis, IBS, Ulcerative Colitis, among other indications.

#### Prevention of Acute GVHD

We have recently completed an exploratory, randomized, double blind, placebo-controlled, Phase 2 "proof of concept" clinical trial of orBec® for the prevention of acute GVHD in patients undergoing myeloablative conditioning regimens with initiation of dosing prior to hematopoietic cell transplantation (HCT) and continuing through the post-transplantation period. The trial was conducted under an investigator-initiated IND by Paul Martin, MD, at the FHCRC and was supported, in large part, by a grant from the National Institutes of Health. We did not receive any direct monetary benefit from this grant. The Phase 2 trial enrolled 140 patients with a 2:1 (orBec®: placebo) randomization plan. Preliminary results from this estimation study indicate that orBec® appears safe and well tolerated in this patient population, but did not achieve statistical significance in the primary endpoint, which was the proportion of patients who developed acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. However, the use of orBec® resulted in fewer cases of more severe acute GVHD grades IIb-IV (21% vs. 33% of patients receiving placebo), although this difference was not statistically significant. This result has the potential to be clinically relevant because GVHD grades IIb-IV are associated with more severe disease involving the skin and liver as well as being associated with poorer outcomes, including mortality rates that approach 100% in the grade IV patient population. Further analysis of the complete dataset continues and is aimed at identifying other potential effects seen with orBec® in preventing acute GVHD.

#### SGX201- Time Release Formulation of oral BDP

We are currently enrolling patients in a Phase 1/2 clinical trial in acute radiation enteritis for which we have received “Fast Track” designation from the FDA. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit an NDA for SGX201 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

SGX201 contains BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in inhalation products for the treatment of patients with allergic rhinitis and asthma. BDP is also the active ingredient in orBec®, currently in Phase 3 and Phase 2 development by Soligenix for the treatment and prevention of GI GVHD, respectively. SGX201 is a time-release formulation of BDP specifically designed for oral use.

Patients with rectal cancer who are scheduled to undergo concurrent radiation and chemotherapy prior to surgery will be enrolled in four dose groups. The objectives of the study are to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. This program is supported in part by a \$500,000 two-year Small Business Innovation Research (“SBIR”) grant awarded by the NIH.

The study is expected to be completed in the first half of 2011.

#### About Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectum, prostate, and vagina. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B12 are not well absorbed.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

There are over 100,000 patients annually in the U.S. who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

#### LPM™ – Leuprolide

Our Lipid Polymer Micelle (“LPM™”) oral drug delivery system is a proprietary platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in pre-clinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a “reverse micelle” that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only



molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

In pre-clinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising pre-clinical data, we anticipate preparing for a Phase 1 study in humans to confirm these findings, pending further funding.

An oral version of leuprolide may provide a significant advantage over the currently marketed “depot” formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide annual sales of more than \$1 billion in recent years. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

#### BioDefense Overview

##### RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin toxin vaccine to be clinically tested in humans. The vaccine is comprised of a recombinant nontoxic derivative of ricin A chain which induces antibodies after immunization. Ricin is a potent glycoprotein toxin, derived from the beans of castor plants. It can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The Centers for Disease Control (“CDC”) has classified ricin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

The in