SOLIGENIX, INC.
Form POS AM
April 20, 2010

As filed with the Securities and Exchange Commission on April 20, 2010.
Registration No. 333-149239

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SOLIGENIX, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	41-1505029
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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)

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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

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 offeringo

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 o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x
(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 20, 2010

PROSPECTUS

Soligenix, Inc.

26,563,613 Shares of Common Stock

This prospectus relates to the sale 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 16, 2010, the last quoted sale price for our common stock as reported on the OTCBB was $0.30 per share.

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 _____, 2010

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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.

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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 statement 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.

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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

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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 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 4,746,192 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 $812,500. 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 121,875 additional shares as a pro rata commitment fee in connection with the purchase by Fusion Capital of the $812,500 of our common stock. We also will issue to Fusion Capital an additional 1,153,125 shares as a commitment fee pro rata as we receive the $7,687,500 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 16, 2010, there were 186,888,036 shares outstanding (125,114,923 shares held by non-affiliates), excluding the 18,031,585 shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of such 18,031,585 shares that may be sold to Fusion Capital and are offered hereby were issued and outstanding as of the date hereof, the 18,031,585 shares would represent approximately 8.80% of the total common stock outstanding, or approximately 14.41% 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. The registration statement was declared effective on April 4, 2008 and the conditions to commence funding were satisfied on April 11, 2008. On April 27, 2009, we filed a post-effective amendment to update the disclosure contained in the registration statement, and the conditions to recommence funding were satisfied on May 14, 2009. We again filed a post-effective amendment on April 20, 2010 to update the disclosure contained in the

registration statement. 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.

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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:

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- 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 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 first 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.

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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.

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.

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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.

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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.

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, 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.

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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.

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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 14 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.

Our stock price has fluctuated over the last year between a high of $0.38 per share to a low of $0.06 per share. As of April 16, 2010, our common stock traded at $0.30 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.

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

Our common stock trades on the Over-The-Counter Bulletin Board ("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 ("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 or quoted on the NASDAQ system, 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 42,527,874 shares of our common stock at a current weighted average exercise price of approximately $0.241; and
- options to purchase approximately 18,847,539 shares of our common stock at a current weighted average exercise price of approximately $0.242

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. Through April 2010, we have issued an additional 2,015,290 shares of common stock and a five-year warrant to purchase 100,000 shares of common stock at $0.303 per share and received an additional $312,500 from the Fusion Capital facility.

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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 for sale by Fusion Capital are freely tradable. It is anticipated that those shares will be sold over a period of up to 18 months from the date of this prospectus. Depending upon market liquidity at the time, a sale of 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 16, 2010 was $0.30 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.

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BUSINESS

Our Business Overview

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. 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.

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
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

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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)

BioTherapeutics Overview

orBec® and oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GI 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. 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 potentially 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 orBec®'s ability 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).

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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 U.S. Food and Drug Administration ("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 ("EMEA") on the design of the Phase 3 clinical trial for orBec®. The EMEA 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 has been initiated and is expected to complete in the first 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.

We have entered into a collaboration agreementwith Numoda Corporation ("Numoda") for the execution of our confirmatory Phase 3 clinical trial of orBec®. Collaborating with Numoda will allow us to take advantage of a scope of services including using their industry benchmarking capabilities to develop an operational and financial plan including the use of a proprietary management and oversight capabilities process. As part of the collaboration, Numoda has agreed to accept our common stock as payment in exchange for a portion of its services in connection with the conduct of the confirmatory Phase 3 clinical trial. To date, we have issued 3,250,447 shares of common stock to Numoda in partial payment for its services.Working with Numoda, we also will be able to take full advantage of early reporting of results to potential licensing partners and others.

We are currently enrolling patients in a randomized, double blind, placebo-controlled, Phase 2 clinical trial of orBec® for the prevention of acute GVHD after allogeneic hematopoietic cell transplantation ("HCT") with myeloablative conditioning regimens. The trial is being conducted by Paul Martin, M.D., at the FHCRC and is being supported, in large part, by a grant from the National Institutes of Health. We will not receive any direct monetary benefit from this grant, but if successful, this funded trial could serve to increase the value of our orBec®/oral BDP program. The Phase 2 trial will seek to enroll up to 138 (92 orBec® and 46 placebo) patients. The primary endpoint of the trial is the proportion of subjects who develop acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. Patients in this study will begin dosing at the start of the conditioning regimen and continue through day 75 following HCT. This trial is expected to complete enrollment in the first half of 2010.

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Mortality Results

	Phase 3 Trial		Phase 2 Trial	
	orBec®	Placebo	orBec®	Placebo
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 significantly different. 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.

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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 Pharmaceuticals, Inc. 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 (inclusive of drug supply) 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 currently available in Named Patient Access Programs ("NPAPs") in South Korea, Latin America, Canada, Singapore, Malaysia, 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.

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.

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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 initiated a Phase 2 trial of orBec® in the prevention of acute GVHD and are expecting to complete enrollment in the first half of 2010. We expect to begin a Phase 2 clinical trial in chronic GI GVHD in the second half of 2010. 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, Irritable Bowel Syndrome, Ulcerative Colitis, among other indications.

SGX201- Time Release Formulation of oral BDP

We have recently initiated 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.

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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.

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.

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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. Ricin is a recombinant derivative of the ricin A chain and 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 potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 entitled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" (http://www.fbi.gov/publications/terror/terrorism2002_2005.pdf). 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 initial Phase 1 clinical trial of RiVax ™ was conducted by Dr. Ellen Vitetta at the University of Texas Southwestern Medical Center (“UTSW”) at Dallas, Soligenix's academic partner. The trial demonstrated that RiVax™ is well tolerated and induces antibodies in humans that neutralize the ricin toxin. The functional activity of the antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injected with serum samples from the volunteers. The outcome of the study was published in the Proceedings of the National Academy of Sciences. A second Phase 1 trial supported by a grant to UTSW is currently underway utilizing an adjuvanted formulation of RiVax™ and is expected to complete in the second half of 2010.

The National Institutes of Health (“NIH”) has previously awarded us two grants: one for $6.4 million and one for $5.2 million for a total of $11.6 million for the development of RiVax™ covering process development, scale-up and current Good Manufacturing Practice (“cGMP”) manufacturing, and pre-clinical toxicology testing pursuant to the FDA’s “animal rule,” which has supported our research from 2004 to present.

On September 21, 2009, we announced that we were awarded a $9.4 Million grant from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the NIH. The grant will fund, over a five-year period, the development of formulation and manufacturing processes for vaccines, including RiVaxTM, that are stable at elevated temperatures. The grant will also fund the development of improved thermostable adjuvants expected to result in rapidly acting vaccines that can be given with fewer injections over shorter intervals. The development of heat-stable vaccines will take advantage of combining several novel formulation processes with well characterized adjuvants that have been evaluated in numerous vaccine field trials. The formulation and process technology funded by the grant will be applied to the further development of RiVaxTM, a subunit vaccine for prevention of ricin toxin lethality and morbidity. The grant will also address the development of manufacturing processes and animal model systems necessary for the pre-clinical characterization of vaccine formulations. Further, the grant will fund the concurrent development of at least one other protein subunit vaccine, which is currently expected to be an anthrax vaccine. This could lead to new subunit vaccines that would bypass current cold chain requirements for storage and distribution. Vaccines to be stored in the Strategic National Stockpile (“SNS”) and used under emergency situations for biodefense are expected to have long-term shelf life.

On April 29, 2008, we announced the initiation of a comprehensive program to evaluate the efficacy of RiVax™ in non-human primates. This study is taking place at the Tulane University Health Sciences Center and will provide data

that will further aid in the interpretation of immunogenicity data obtained in the human vaccination trials.

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SGX202 – Oral BDP for GI Radiation Injury

On September 12, 2007, we announced that our academic partner, the Fred Hutchinson Cancer Research Center ("FHCRC"), received a $1 million grant from the NIH to conduct pre-clinical studies of oral beclomethasone dipropionate (oral BDP, also the active ingredient in orBec®) for the treatment of GI radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this work is successful and it will enhance the value of our oral BDP programs. The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studies will compare overall survival and markers of intestinal cell regeneration when the drug regimens are added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC. Our rights to the use of SGX202 are through our license with George McDonald.

The Drug Approval Process

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FDA and applicable agencies in other countries. Testing, manufacturing, commercialization, advertising, promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation by government authorities in the U.S. and other countries. All products must go through a series of tests, including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary to protect the safety of subjects.

Our products will require regulatory clearance by the FDA and by comparable agencies in other countries, prior to commercialization. The nature and extent of regulation differs with respect to different products. In order to test, produce and market certain therapeutic products in the U.S., mandatory procedures and safety standards, approval processes, manufacturing and marketing practices established by the FDA must be satisfied.

An Investigational New Drug ("IND") application is required before human clinical testing in the U.S. of a new drug compound or biological product can commence. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

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With certain exceptions, once successful clinical testing is completed, the sponsor can submit an NDA for approval of a drug. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of an NDA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

In the U.S., the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the Federal Food, Drug, and Cosmetic Act involving medical devices.

For the development of biodefense vaccines, such as RiVaxTM, the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still have to establish that the vaccine and countermeasures it is 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 benefit-risk 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 the Company 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.

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Marketing Strategies

Pursuant to the collaboration and supply agreement with Sigma-Tau, we granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico.

We are actively seeking a commercialization partner for orBec® and oral BDP outside of North America as well as for our LPMTM – Leuprolide program.

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of our biodefense vaccine products. We may market our biodefense vaccine products directly to government agencies. We believe that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we currently have. Another source of competing technologies is universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, and we face competition from other companies to acquire rights to those technologies.

orBec® Competition

Competition is intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat GVHD by suppressing the immune system through various mechanisms. Some companies, including Sangstat, Abgenix, and PDL BioPharma, Inc., are developing monoclonal antibodies to treat GVHD. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat GVHD. All of these products are in various stages of development. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant-related therapeutics. We face potential competition from Osiris Therapeutics if its product Prochymal for the treatment of GVHD is successful in reaching the market. Kiadis Pharma is also developing products for the treatment of GVHD. In addition, there are investigator-sponsored clinical trials exploring the use of approved drugs such as Enbrel®, which has been approved by the FDA for the treatment of rheumatoid arthritis, in the treatment of GVHD. We believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make orBec® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product RemicadeTM for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®. Entocort® is structurally similar to beclomethasone dipropionate, and the FDA-approved Entocort for Crohn's disease late in 2001. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis called Colazal®. Chiesi Pharmaceuticals ("Chiesi") markets a delayed-release oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPERTM for ulcerative colitis and may seek marketing approval in Italy and other European countries. In the U.S., Eurand N.V. ("Eurand") has licenses from Chiesi to the same formulation as CLIPPERTM and is developing it for ulcerative colitis. Eurand has also received Orphan Drug Designation for the compound in pediatric ulcerative colitis patients.

Several companies have also established various colonic drug delivery systems to deliver therapeutic drugs to the colon for treatment of Crohn's disease. These companies include Ivax Corporation, Inkine Pharmaceutical Corporation, and Elan Pharmaceuticals, Inc. Other approaches to treat gastrointestinal disorders include antisense and gene therapy. Isis Pharmaceuticals, Inc. is in the process of developing antisense therapy to treat Crohn's disease.

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BioDefense Vaccine Competition

We face competition in the area of biodefense vaccines from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with the our technologies. Acambis, Inc., Dynavax, Emergent Biosolutions (formerly Bioport Corporation), VaxGen, Inc., Chimerix, Inc., Human Genome Sciences, Inc., Coley Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmathene, SIGA Pharmaceuticals and others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. For example, Avecia Biotechnology, Inc. has received NIH contracts to develop a next generation injectable anthrax vaccine. VaxGen received an approximately $900 million procurement order from the U.S. government to produce and deliver 75 million doses of Anthrax vaccine. This contract was rescinded in January 2007 by the U.S. Department of Health and Human Services ("HHS") because of the inability of Vaxgen to enter into Phase 2 clinical trials according to contract timelines. Several companies have received development grants from the NIH for biodefense products. For example, Coley Pharmaceuticals, Inc. has received a $6 million Department of Defense ("DOD") grant to develop vaccine enhancement technology. Dynport Vaccine Company, LLC, a prime contractor with the DOD, currently has a $200 million contract to develop vaccines for the U.S. military, including a multivalent botulinum toxin vaccine. Although we have received significant grant funding to date for product development, we have not yet been obtained contract awards for government procurement of products.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We are the exclusive licensee of an issued U.S. patent that covers the use of orBec® for the prevention and treatment of GI GVHD. We also have "Orphan Drug" designations for orBec® in the U.S. and in Europe. Our Orphan Drug designations provide for seven years of post approval marketing exclusivity in the U.S. and ten years exclusivity in Europe for the use of orBec® in the treatment of GI GVHD. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the seven year post-approval exclusivity provided by the Orphan Drug Act of 1983.

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orBec® License Agreement

In November 1998, we entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, M.D., including the right to grant sublicenses, for the rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDonald receives $80,000 per annum as a consultant.

We also executed an exclusive license to patent applications for "Use of Anti-Inflammatories to Treat Irritable Bowel Syndrome" from the University of Texas Medical Branch-Galveston. Under the license agreements, we will be obligated to make performance-based milestone payments, as well as royalty payments on any net sales of oral BDP.

RiVax™ Intellectual Property

In January 2003, we executed a worldwide exclusive option to license patent applications with University of Texas Southwestern Medical Center ("UTSW") for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine and, in October 2004, we negotiated the remaining oral rights to the ricin vaccine. Our license obligates us to pay $50,000 in annual license fees. Through this license, we have rights to the issued patent number 7,175,848 entitled "Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin." This patent includes methods of use and composition claims for RiVax™.

Research and Development Expenditure

We spent approximately $4,500,000 and $1,600,000 in the years ended December 31, 2009 and 2008, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2009 and 2008 are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

Employees

As of April 16, 2010, we had 12 full-time employees, 6 of whom are Ph.D.s.

Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes and our unaudited consolidated interim financial statements and their notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Forward-Looking Statements."

Our Business Overview

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 program 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.

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Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, we capitalized all applicable outside legal and filing costs incurred in the procurement and defense of patents.

We capitalize and amortize intangibles over their expected useful life – generally a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. We capitalize intangible assets' alternative future use as referred to in FASB ASC 350, Intangibles – Goodwill and Other and FASB ASC 730, Research and Development.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

Research and Development Costs

Research and development costs are charged to expense when incurred. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries and employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Revenue Recognition

Our revenues are generated from NIH grants, the achievement of licensing milestones, and NPAP sales of orBec®. The revenue from NIH grants are based upon subcontractor costs and internal costs incurred that are specifically covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. Licensing milestone revenues are recorded when earned. Revenue from NPAP sales of orBec® are recorded when the product is shipped.

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Stock-Based Compensation

From time to time, we issue common stock to vendors, consultants, and employees as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

We determine stock-based compensation expense for options, warrants and shares of common stock granted to non-employees in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The option's price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

New Accounting Pronouncements

See Note 2, New Accounting Pronouncements, for a discussion of new accounting pronouncements.

Material Changes in Results of Operations

Year Ended December 31, 2009 Compared to 2008

For the year ended December 31, 2009, we had a net loss of $6,034,453 as compared to a net loss of $3,422,027 for the prior year, representing an increase of $2,612,426 or 76%. This increase is primarily attributed to increased spending of $2,971,052 in research and development for the year ended December 31, 2009 over 2008 related to the preparation for and conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. For the year ended December 31, 2009, there was also an increase in general and administrative expenses of $339,532, which reflects the $270,000 expense recorded in first quarter 2008 related to the Fusion Capital commitment shares, offset by staffing and other corporate cost increases this year.

For the year ended December 31, 2009, revenues and associated costs relate to NIH grants awarded in support of our ricin, botulinum and thermostable vaccines development and from the NPAP sales of orBec®. For the year ended December 31, 2009, we had revenues of $2,816,037 as compared to $2,310,265 for the prior year, representing an increase of $505,772, or 22%. During 2009, we received a $1 million clinical milestone payment from Sigma Tau, our collaborative partner on the orBec® Phase 3 study. The increase in revenues generated by this one-time milestone payment was offset by decreases in NIH grant revenues as we reached the end of our earlier NIH grants before the work under our newer grants had commenced. Included in those revenue figures for the year ended December 31, 2009, we also recorded revenues of $56,000 from NPAP sales of orBec®, compared to $40,618 recorded in the prior year.

We incurred costs related to that revenue in the year ended December 31, 2009 and 2008 of $1,483,641 and $1,886,431, respectively, representing a decrease of $402,790, or 21%. This decrease follows from the decrease in NIH grant revenues discussed above.

Our gross profit for the year ended December 31, 2009 was $1,332,396 as compared to $423,834 for the prior year, representing an increase of $908,562, or 214%. This increase is almost entirely explained by the $1 million clinical milestone revenue recorded in 2009 for which there were no corresponding costs.

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Research and development spending increased by $2,971,052, or 191%, to $4,523,375, for the year ended December 31, 2009 as compared to $1,552,323 for the prior year. This increase is primarily related to the preparation for and conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD.

General and administrative expenses increased $339,532, or 17%, to $2,281,251 for the year ended December 31, 2009, as compared to $1,941,719 for the prior year reflecting staffing and other corporate cost increases this year.

Stock-based compensation expenses related to research and development increased $28,666, or 16%, to $210,834 for the year ended December 31, 2009, as compared to $182,168 for the prior year. Stock-based compensation expenses related to general and administrative increased $164,784, or 81%, to $368,232 for the year ended December 31, 2009, as compared to $203,448 for the prior year. These increases were related to stock options that were issued to new employees hired in 2009 and for options issued in the last quarter of 2008 that began vesting in 2009.

Net interest income for the year ended December 31, 2009 was $19,242 as compared to $33,797 for the prior year, representing a decrease of $14,555, or 43%. This decrease was due to substantially lower interest rates earned on cash balances in 2009 versus the prior year.

Business Segments

We had two active business segments for the year ended December 31, 2009 and December 31, 2008: BioDefense and BioTherapeutics.

Revenues for the BioDefense business segment for the year ended December 31, 2009 were $1,670,536 as compared to $2,269,647 for the year ended December 31, 2008, representing a decrease of $599,111, or 26%. This decrease is primarily attributed to a reduction in NIH grant revenues as we reached the end of our earlier NIH grants focusing on RiVax and botulinum vaccines before the work under our new thermostable vaccine technology grant had commenced. Revenues for the BioTherapeutics business segment for the year ended December 31, 2009 were $1,145,501 as compared to $40,618 for the year ended December 31, 2008, representing an increase of $1,104,883. This substantial increase is a result of the receipt of a $1 million clinical milestone payment from Sigma Tau in 2009 upon the initiation of enrollment in the confirmatory Phase 3 clinical trial of orBec®.

Loss from operations for the BioDefense business segment for the year ended December 31, 2009 was $389,157 as compared to $132,272 for the year ended December 31, 2008, representing an increase of $256,885, or 194%. This increase is primarily attributed to a reduction in NIH grant revenues as we reached the end of our earlier NIH grants focusing on RiVax and botulinum vaccines before the work under our new thermostable vaccine technology grant had commenced. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2009 was $3,444,838 as compared to $1,556,429 for the year ended December 31, 2008, representing an increase of $1,888,409, or 121%. This increase is primarily attributed the preparation for and conduct of the confirmatory Phase 3 clinical trial of orBec®, offset to some degree by the receipt of a $1 million clinical milestone payment from Sigma Tau in 2009.

Amortization and depreciation expense for the BioDefense business segment for the year ended December 31, 2009 was $91,420 as compared to $85,354 for the year ended December 31, 2008, representing an increase of $6,066, or 7%, primarily related to newly capitalized patent support costs in 2009. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2009 was $77,496 as compared to $58,829 for the year ended December 31, 2008, representing an increase of $18,667, or 32%, primarily related to newly capitalized patent support costs in 2009.

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Financial Condition and Liquidity

Cash and Working Capital

As of December 31, 2009, we had cash and cash equivalents of approximately $7,692,000 as compared to $1,475,000 as of December 31, 2008, representing an increase of $6,217,000, or 421%, over the prior year. As of December 31, 2009, we had working capital of approximately $6,690,000 as compared to working capital of $537,000 as of December 31, 2008, representing an increase of $6,153,000. The increase was the result of the $10.9 million in proceeds from the sale of our common stock and warrants to accredited investors and a collaborative partner, less the cash used in operating and investing activities over the period. We have used equity instruments in the past to provide a portion of the compensation due to our employees, vendors and collaborative partners, and expect to continue to do so in the foreseeable future. For the year ended December 31, 2009, our cash used in operating activities was approximately $4,603,000, compared to $2,788,000 for the prior year, representing an increase of $1,815,000, or 65%. This increase primarily relates to the preparation for and conduct of our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD.

Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, proceeds from our grant-funded programs, revenues collected under the NPAP's, and potential proceeds from the Fusion Capital transaction, we believe that our current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures beyond the first quarter of 2011.

Our plans with respect to our liquidity management include the following:

- We have $10 million in active grant funding still available to support our research programs in 2010 and beyond. Additionally, we have submitted additional grant applications for further support of these programs and others with various funding agencies, and have received encouraging feedback to date on the likelihood of funding.
- We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future.
- We have approximately $7.7 million in available capacity under our Fusion Capital equity facility. Although we have historically drawn amounts in modest amounts under this agreement, we could draw more within certain contractual parameters.
- We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our research and development expenditures for the next 12 months to be approximately $7,500,000. We anticipate grant revenues in the next year to offset research and development expenses for the development of our thermostable vaccine technology and the development of SGX201 in radiation enteritis in the amount of approximately $1,600,000, with $700,000 of that total amount contributing towards our overhead expenses.

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The table below details our costs by program for each of the two years ended December 31, 2009:

	2009	2008
Research & Development Expenses		
orBec®	$3,211,682	$921,562
RiVax™ & Thermostable Vaccines	1,264,218	312,486
BT-VACC™	31,167	201,529
Oraprine™	6,000	4,500
LPM™ Leuprolide	10,308	112,246
Total	$4,523,375	$1,552,323
Reimbursed under NIH Grants		
orBec®	$162,106	$122,551
RiVax™ & Thermostable Vaccines	1,321,535	1,681,274
BT-VACC™	-	82,606
Total	$1,483,641	$1,886,431
Grand Total	$6,007,016	$3,438,754

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the years ended December 31, 2009 or 2008.

Contractual Obligations

We have a contractual obligation of approximately $3.3 million as of December 31, 2009 in connection with a collaboration with Numoda for the execution of our confirmatory Phase 3 clinical trial of orBec® that began in September 2009 and is expected to complete in first half of 2011.

We have several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved; however, there can be no assurance that clinical or commercialization success will occur.

On April 1, 2009, we entered into a sublease agreement through March 31, 2012 for office space in Princeton, New Jersey. We were required to provide 4 months of rent as a security deposit. The rent for the first 18 months will be approximately $7,500 per month, or approximately $17.00 per square foot on an annualized basis. This rent increases to approximately $7,650 per month, or approximately $17.50 per square foot on an annualized basis, for the remaining 18 months.

On April 24, 2008, we signed a three-year lease for a copier.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

As a result of the above agreements, we have future contractual obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total

2010	$ 3,013,640	$95,398	$3,109,038
2011	631,440	92,699	724,139
2012	155,000	22,950	177,950
2013	75,000	-	75,000
2014	75,000	-	75,000
Total	$ 3,950,080	$211,047	$4,161,127

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DIRECTORS AND EXECUTIVE OFFICERS

The following table contains information regarding the current members of the Board of Directors and executive officers: The ages of individuals are provided as of April 16, 2010:

Name	Age	Position
Christopher J. Schaber, Ph.D.	43	Chairman of the Board, Chief Executive Officer and President
Cyrille F. Buhrman	37	Director
Gregg A. Lapointe, C.P.A., M.B.A.	51	Director
Robert J. Rubin, M.D.	64	Director
Evan Myrianthopoulos	45	Chief Financial Officer, Senior Vice President and Director
Brian L. Hamilton, M.D., Ph.D.	62	Chief Medical Officer and Senior Vice President
Robert N. Brey, Ph.D.	59	Chief Scientific Officer and Senior Vice President
Christopher P. Schnittker, C.P.A.	41	Vice President of Administration, Controller and Corporate Secretary

Christopher J. Schaber, Ph.D. has been our President and Chief Executive Officer and a director since August 2006. He was appointed interim Chairman of the Board on October 8, 2009. Dr. Schaber has served on the boards of directors of both the Alliance for BioSecurity and BioNJ since May 2008 and January 2009, respectively, and represents Soligenix on the corporate councils of both the National Organization for Rare Diseases (“NORD”) and the American Society for Blood and Marrow Transplantation (“ASBMT”) since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising in excess of $150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his B.A. degree from Western Maryland College, his M.S. degree in Pharmaceutics from Temple University School of Pharmacy and his Ph.D. degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as executive senior officer with our Company and Discovery Laboratories, Inc., and as a member of the boards of directors of the Alliance for BioSecurity and BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Cyrille F. Buhrman has been a director since June 2007. Mr. Buhrman is Chairman of the Pacific Healthcare Group of Companies, a full-service regulatory affairs, commercialization and distribution company, focusing on specialty pharmaceuticals, medical supplies, medical technology, OTC and consumer health products across the Asian region. In addition to serving on the Board of Soligenix, Mr. Buhrman has served on the boards of directors of Canyon Pharmaceuticals, a privately-held company specialty pharmaceutical company based in Basel, Switzerland and serves on the boards of directors of several other privately-held pharmaceutical and medical technology companies in the Asia Pacific region. Mr. Buhrman also heads up his own private investment fund that specializes in

the biotechnology and pharmaceutical industries. Mr. Buhrman is also one of our largest shareholders. Mr. Buhrman was selected to serve as a member of our Board of Directors because of his experience as a CEO of a pharmaceutical company, as a member of the boards of several pharmaceutical, and medical device companies and as an investor in the biotechnology and pharmaceutical industries.

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Gregg Lapointe, C.P.A., M.B.A. has been a director since March 10, 2009. Mr. Lapointe has served on the Board of Directors of the Pharmaceuticals Research and Manufacturers of America ("PhRMA") and has been a member of the Corporate Council of NORD for several years. He has served in varying roles for Sigma-Tau, a private biopharmaceutical company, since September 2001, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer since April 2008. From May, 1996 to August, 2001, he served as Vice President of Operations and Vice President, Controller of AstenJohnson, Inc. (formerly JWI Inc.). Prior to that, Mr. Lapointe spent several years in the Canadian medical products industry in both distribution and manufacturing. Mr. Lapointe began his career at Price Waterhouse. Mr. Lapointe received his B.A. degree in Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill University and his M.B.A. degree from Duke University. He is a C.P.A. in the state of Illinois and a Chartered Accountant in Ontario, Canada. Mr. Lapointe was selected to serve as a member of our Board of Directors because of his significant experience in the areas of global strategic planning and implementation, business development, corporate finance, and acquisitions, and his experience as an executive officer and board member in the pharmaceutical medical products industries.

Robert J. Rubin, M.D. has been a director since October 8, 2009. Dr. Rubin has also been a clinical professor of medicine at Georgetown University since 1995. From 1987 to 2001, he was president of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal for ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as the Assistant Surgeon General in the United States Public Health Service. Dr. Rubin is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Evan Myrianthopoulos has been a director since 2002 and is currently our Chief Financial Officer and Senior Vice President, after joining us in November of 2004 as President and Acting Chief Executive Officer. From November 2001 to November 2004, he was President and founder of CVL Advisors Group Inc., a financial consulting firm specializing in the biotechnology sector. Prior to founding CVL Advisors Group, Inc., Mr. Myrianthopoulos was a co-founder of Discovery Laboratories, Inc. During his tenure at Discovery Laboratories, Inc. from June 1996 to November 2001, Mr. Myrianthopoulos held the positions of Chief Financial Officer and Vice President of Finance, where he was responsible for raising approximately $55 million in four private placements. He also helped negotiate and manage Discovery Laboratories, Inc.'s mergers with Ansan Pharmaceuticals and Acute Therapeutics, Inc. Prior to co-founding Discovery Laboratories, Inc., Mr. Myrianthopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm from October 1995 to December 1997. Prior to joining Paramount Capital Investments, LLC, Mr. Myrianthopoulos was a managing partner at a hedge fund and also held senior positions in the treasury department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr. Myrianthopoulos holds a B.S. degree in Economics and Psychology from Emory University. Mr. Myrianthopoulos was selected to serve as a member of our Board of Directors because of his experience as principal financial officer and principal executive officer of our Company and Discovery Laboratories and his experience in raising capital.

Brian L. Hamilton, M.D., Ph.D. has been Chief Medical Officer and Senior Vice President since March 11, 2009. His academic career at the University of Washington and the University of Miami focused on the use of bone marrow transplantation to treat children with congenital immune deficiency, with research in the immunobiology of GVHD. In the pharmaceutical industry, he has worked with both large pharmaceutical companies (Astra, USA and Wyeth) and

several biotechnology companies. From December 2001 to June 2004, he was Senior Director of Clinical Research with Wyeth Research. From June 2004 to March 2006, he was Vice President for Clinical and Regulatory Affairs at Merrimack Pharmaceutical. He was Chief Medical Officer with BioVex from September 2006 to March 2007. He was a consultant in clinical development as Medical Director with Biopharm Solutions, Inc. from March 2007 to October 2008. From October 2008 to March 2009, he was Acting Vice President of Medical Affairs with Ziopharm Oncology. He has expertise in clinical development and regulatory affairs with small molecules, biologics, vaccines, and genetically modified oncolytic viruses in oncology, hematology, rheumatology, and immunology. At Astra, USA, he had a significant role in the clinical development and registration of both Pulmicort Turbuhaler for the treatment of patients with asthma and Rhinocort Aqua for the treatment of patients with allergic rhinitis. Dr. Hamilton received his M.D. and Ph.D. degrees from the University of Washington, with post-graduate training in Pediatrics, Allergy, Immunology, and Oncology.

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Robert N. Brey, Ph.D. has been with the Company since January 1996, and is currently our Chief Scientific Officer and Senior Vice President. He has also held the positions of Vice President Vaccine Development and Vice President of Research and Development. He also has held Scientific, Management and Project Management positions in the Lederle-Praxis division of American Cyanamid, now a division of Wyeth, in which he participated in the successful development of a vaccine for Haemophilius influenzae meningitis, and a vaccine for pneumonia. While at Lederle-Praxis, Dr. Brey was Manager of Molecular Biology Research for vaccines and Project Manager for development of oral vaccines from 1985 through 1993. From 1993 through 1994, Dr. Brey served as Director of Research and Development of Vaxcel, in which he was responsible for developing adjuvant technology and formulations for improved vaccines. From 1994 through 1996, Dr. Brey established an independent consulting group, Vaccine Design Group, to identify and develop novel vaccine technologies and platforms. Before entering into drug and vaccine delivery, he held senior scientific positions at Genex Corporation from 1982 through 1986. Dr. Brey received a B.S. degree in Biology from Trinity College in Hartford, Connecticut, his Ph.D. degree in Microbiology from the University of Virginia and performed postdoctoral studies at MIT with Nobel Laureate Salvador Luria.

Christopher P. Schnittker, C.P.A. has been our Vice President of Administration, Controller and Corporate Secretary since July 2009. He has more than 19 years of financial management experience primarily in publicly-held life science companies. From June 2000 until joining Soligenix, Mr. Schnittker was a Vice President and Chief Financial Officer of several publicly-held biotechnology and specialty pharmaceutical companies, including: VioQuest Pharmaceuticals Inc. (from July 2008 until joining Soligenix); Micromet, Inc. (from October 2006 through December 2007); Cytogen Corporation (from September 2003 through May 2006); and Genaera Corporation (from June 2000 through August 2003). From December 1997 through June 2000, he was Director of Finance and Controller of GSI Commerce, an e-commerce technology company. From June 1995 through December 1997, he served in various financial reporting and internal control manager roles with Rhône-Poulenc Rorer Pharmaceuticals Inc. (now part of the Sanofi Aventis Group). From September 1990 through June 1995, he was a member of the Audit and Assurance Services division at Price Waterhouse LLP (now PricewaterhouseCoopers LLP), working largely with the firm's pharmaceutical and technology clients. Mr. Schnittker received his Bachelor's degree in Economics and Business, with a concentration in Accounting, from Lafayette College in 1990 and is a currently-licensed Certified Public Accountant in the State of New Jersey.

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EXECUTIVE COMPENSATION

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2009 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2009 (collectively, the "Named Executive Officers").

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber1	CEO & President	2009	$ 337,709	$ 120,000	-	$ 24,737	$ 482,446
		2008	$ 300,000	$ 100,000	$ 127,120	$ 24,844	$ 551,964
Evan Myrianthopoulos2	CFO & Senior VP	2009	$ 202,605	$ 70,000	-	$ 24,811	$ 297,416
		2008	$ 200,000	$ 50,000	$ 54,480	$ 23,474	$ 327,954
Brian L. Hamilton3	CMO & Senior VP	2009	$ 206,400	$ 60,000	$ 87,400	$ 26,843	$ 380,643

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[1] Dr. Schaber deferred payment of his 2008 annual bonus of $100,000 until February 28, 2009 and his 2009 annual bonus of $120,000 until January 15, 2010. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation for 2008 and 2009 represent insurance costs.

[2] Mr. Myrianthopoulos deferred payment of his 2008 annual bonus of $50,000 until February 28, 2009 and his 2009 annual bonus of $70,000 until January 15, 2010. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation for 2008 and 2009 represent insurance costs.

3 Dr. Hamilton joined the Company in April 2009. He deferred his 2009 annual bonus of $60,000 until January 15, 2010. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation for 2009 represents insurance costs.

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, Ph.D. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. This employment agreement was renewed in December 27, 2007 for a term of three years. We agreed to issue him options to purchase 2,500,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependants. No unvested options shall vest beyond the termination date. Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) remained unchanged from 2006 with the 2007 renewal. He will be paid nine months of severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Dr.

Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

In December 2004, we entered into a three-year employment agreement with Evan Myrianthopoulos. Pursuant to this employment agreement we agreed to pay Mr. Myrianthopoulos a base salary of $185,000 per year. After one year of service Mr. Myrianthopoulos would be entitled to a minimum annual bonus of $50,000. This employment agreement was renewed in December 27, 2007 for a term of three years. We agreed to issue him options to purchase 500,000 shares of our common stock, with the options vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Mr. Myrianthopoulos six months of severance subject to set off, as well as any unpaid bonuses and accrued vacation would become payable.

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No unvested options shall vest beyond the termination date. Mr. Myrianthopoulos also received 150,000 options, vested immediately when he was hired in November 2004, as President and Acting Chief Executive Officer. Mr. Myrianthopoulos' monetary compensation (base salary of $200,000 and bonus of $50,000) remained unchanged from 2006 with the 2007 renewal. He will be paid six months of severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Myrianthopoulos' options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become property of Mr. Myrianthopoulos' immediate family.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber, Mr. Myrianthopoulos and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from the Company and/or our stockholders to a third party: 1,000,000 common shares to Dr. Schaber and 750,000 common shares to Mr. Myrianthopoulos. The amended agreements include our obligation to issue such shares to the executives if such event occurs.

In March 2009, we entered into a two-year employment agreement with Brian L. Hamilton, M.D., Ph.D. Pursuant to this employment agreement we agreed to pay Dr. Hamilton a base salary of $270,000 per year and a minimum annual bonus of $70,000. We agreed to issue him options to purchase 1,000,000 shares of our common stock, with one quarter immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Hamilton six months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Hamilton and his dependants. No unvested options shall vest beyond the termination date. Upon a change in control of the Company due to merger or acquisition, all of Dr. Hamilton's options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Hamilton's immediate family.

On March 27, 2009, the Compensation Committee approved the increase in salaries for Dr. Schaber to $350,000 and Mr. Myrianthopoulos to $230,000. On December 1, 2009, the Compensation Committee approved the increase in salaries for Dr. Hamilton to $280,000, effective January 1, 2010. Dr. Schaber's and Mr. Myrianthopoulos' salaries were not changed at this time.

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Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2009. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber	2,500,000	-	-	$ 0.27	8/28/2016
	731,250	168,750	168,750	$ 0.47	8/29/2017