

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

Christopher J. Schaber, Ph.D.

President and Chief Executive Officer

Soligenix, Inc.

29 Emmons Drive, Suite C-10

Princeton, New Jersey 08540

(609) 538-8200

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

with copies to:

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

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

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

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a
smaller reporting
company)

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.

EXPLANATORY NOTE

This Post-Effective Amendment No. 4 (this “Amendment”) to the Registration Statement on Form S-1 (File No. 333-192908) (the “Original Registration Statement”), of Soligenix, Inc. (the “Company”) is being filed pursuant to the undertakings in the Original Registration Statement to update and supplement the information contained in the Original Registration Statement, which was originally declared effective by the Securities and Exchange Commission on January 15, 2014.

For the convenience of the reader, this Amendment sets forth the Original Registration Statement in its entirety, as amended by this Amendment. This Amendment is being filed to incorporate certain information from the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

No additional securities are being registered under this Amendment. All applicable registration fees were paid at the time of the filing of the Original Registration Statement. Accordingly, we hereby amend the Original Registration Statement, as amended and supplemented through the date hereof, by filing this Amendment, which relates to the registration of 3,905,440 shares of common stock, par value \$0.001 per share, being registered for resale by the selling stockholder listed herein.

The information in this prospectus is not complete and may be changed. The selling stockholder shall 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 or other jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED APRIL 13, 2016

SOLIGENIX, INC.

3,905,440 SHARES OF COMMON STOCK

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

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

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

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

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

Our common stock is currently quoted on the OTCQB market under the symbol “SNGX”. On April 11, 2016, the last quoted sale price of our common stock as reported on the OTCQB was \$0.76 per share.

Investing in our securities involves significant risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 6.

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

The date of this prospectus is _____, 2016

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

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

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

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PROSPECTUS SUMMARY

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

Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a first-in-class photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma (“CTCL”), proprietary formulations of oral beclomethasone 17,21-dipropionate (“BDP”) for the prevention/treatment of gastrointestinal (“GI”) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203) and acute radiation enteritis (SGX201), and our novel innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases (“NIAID”), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our government contracts with the Biomedical Advanced Research and Development Authority (“BARDA”) and NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

An outline for our business strategy follows:

Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;

Initiate a Phase 3 clinical trial of SGX203, for the treatment of pediatric Crohn's disease;

Continue to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study in the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;

Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 2b/3 protocol of SGX942 in the treatment of oral mucositis in head and neck cancer patients;

Continue development of RiVax™ in combination with our ThermoVax® technology, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS;

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

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

Explore other business development and merger/acquisition strategies.

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The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 clinical trial initiated in the second half of 2015, with data expected in the second half of 2016
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial initiated in the second half of 2013, with positive preliminary results reported in the second half of 2015; seek to obtain FDA agreement on the Phase 2b/3 protocol in the second half of 2016
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 3 clinical trial planned for the second half of 2016, with data expected in the first half of 2018
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2017

Vaccine Thermostability Platform**

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

BioDefense Product Candidates**

Soligenix Product Candidate	Indication	Stage of Development
RiVax™	Vaccine against	Phase 1B trial complete, safety and neutralizing antibodies for protection demonstrated;

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Ricin Toxin Poisoning Phase 1/2 trial planned for the second half of 2016

OrbeShield® Therapeutic against GI ARS Pre-clinical program initiated

SGX943 Melioidosis Pre-clinical

** Contingent upon continued government contract and grant funding.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to “Immunotherapeutics, Inc.” We changed our name to “Endorex Corp.” in 1996, to “Endorex Corporation” in 1998, to “DOR BioPharma, Inc.” in 2001, and finally to “Soligenix, Inc.” in 2009. 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.

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The Offering

On November 18, 2013, we entered into the Purchase Agreement with Lincoln Park, pursuant to which we sold to Lincoln Park 285,714 shares of our common stock for \$600,000 and Lincoln Park has agreed to purchase from us up to an aggregate of \$10 million of our common stock (subject to certain limitations) from time to time over a 36-month period for a total of \$10.6 million. Also on November 18, 2013, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park, pursuant to which we have filed with the U.S. Securities and Exchange Commission (the “SEC”) the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the “Securities Act”), the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Through April 11, 2016, we have sold to Lincoln Park an aggregate of 1,335,714 shares under the Purchase Agreement for aggregate gross proceeds of approximately \$2.4 million. In addition, we have issued 119,747 shares to Lincoln Park as a commitment fee. Other than the foregoing, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the post-effective amendment to the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 75,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also increase the amount of our common stock to be purchased under certain circumstances to up to 100,000 shares but not exceeding \$750,000 per purchase plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than \$1.00 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of April 11, 2016, there were 31,369,522 shares of our common stock outstanding, of which 26,583,204 shares were held by non-affiliates, excluding the 1,455,461 shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to \$10,600,000 of our common stock to Lincoln Park only 3,905,440 shares of our common stock are being offered under this prospectus, which represents (i) 1,335,714 shares that we have sold to Lincoln Park under the Purchase Agreement, (ii) 119,747 shares that we have issued to Lincoln Park as a commitment fee, (iii) an additional 2,350,000 shares which may be issued to Lincoln Park in the future under the Purchase Agreement and (iv) 99,979 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell shares to Lincoln Park under the Purchase Agreement. The additional commitment shares are issued pro rata as Lincoln Park purchases up to \$10,600,000 of our common stock as directed by us. For example, if we elect, at our sole discretion, to require

Lincoln Park to purchase \$100,000 of our stock then we would issue 1,221 shares of the pro rata commitment fee, which is the product of \$100,000 (the amount we have elected to sell) divided by \$10,000,000 (the total amount we can sell Lincoln Park under the Purchase Agreement) multiplied by 122,070 (the total number of pro rata commitment shares), rounded up or down to the nearest whole share. The pro rata commitment shares will only be issued pursuant to this formula as and when we elect at our discretion to sell stock to Lincoln Park. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. If all of the 3,905,440 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 11.6% of the total number of shares of our common stock outstanding and 14.7% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 3,905,440 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

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Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

Securities Offered

Common Stock offered by the selling stockholder

3,905,440 shares consisting of:

119,747 commitment shares that we have issued to Lincoln Park;
1,335,714 shares that we have issued to Lincoln Park under the Purchase Agreement;
2,350,000 shares that we may sell in the future to Lincoln Park under the Purchase Agreement; and
99,979 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell additional shares to Lincoln Park under the Purchase Agreement.

Common stock outstanding prior to the offering

31,369,522 shares, as of April 11, 2016, including 1,335,714 shares issued to Lincoln Park under the Purchase Agreement and 119,747 commitment shares previously issued to Lincoln Park under the Purchase Agreement (and included in this offering).

Common stock to be outstanding after giving effect to the total issuance of 3,905,440 shares to Lincoln Park under the Purchase Agreement registered hereunder

33,819,501 shares.

Shares issuable option exercise of outstanding options and warrants

The total number of shares of our common stock outstanding prior to the offering and to be outstanding after giving effect to the total issuance of 3,905,440 shares to Lincoln Park under the Purchase Agreement registered hereunder, excludes the following:

2,453,000 shares of common stock reserved for future issuance under our equity incentive plans. As of April 11, 2016, there were options to purchase 2,824,737 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$2.10 per share; and

4,926,119 shares of common stock issuable upon exercise of outstanding warrants as of April 11, 2016 with a weighted average exercise price of \$0.74 per share.

Use of proceeds

We will not receive any proceeds from the sale of the shares of common stock by Lincoln Park in this offering. However, we may receive up to \$10,600,000 from sales of shares under the Purchase Agreement, including up to approximately \$8.2 million from future sales. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used to further develop our product candidates and for general corporate purposes. See “Use of Proceeds.”

Risk factors

This investment involves a high degree of risk. See “Risk Factors” for a discussion of factors you should consider carefully before making an investment decision.

OTC Markets (OTCQB) symbol

SNGX

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RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information about these risks contained in this prospectus, as well as the other information contained in this prospectus generally, before deciding to buy our securities. Any of the risks we describe below could adversely affect our business, financial condition, operating results or prospects. The market prices for our securities could decline if one or more of these risks and uncertainties develop into actual events and you could lose all or part of your investment. 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 this prospectus, including our financial statements and the related notes.

Risks Related to our Business

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

We have experienced significant losses since inception and, at December 31, 2015, had an accumulated deficit of approximately \$146.9 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2015, we had approximately \$4.9 million in cash available. Based on our projected budgetary needs, funding from existing contracts and grants over the next two years and sales to the purchasers under our existing equity lines, we expect to be able to maintain the current level of our operations for at least the next 12 months.

We have sufficient funds through our existing biodefense grant facilities from the NIAID, a division of the National Institutes of Health (the “NIH”), and BARDA to finance our biodefense projects for the next six years. In September 2014, we entered into a contract with the NIH for the development of RiVax™ to protect against exposure to ricin toxin that would provide up to \$24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. In September 2013, we entered into contracts with the NIH and BARDA for the development of OrbeShield® that would provide up to \$32.7 million of funding in the aggregate if options to extend the contracts are exercised by BARDA and the NIH. In September 2009, we received a NIAID grant for approximately \$9.4 million for the development of our biodefense programs. In July 2012, we received an additional Small Business Innovation and Research (“SBIR”) grant from NIAID for \$600,000 and in February 2014, we were awarded a one-year NIAID SBIR grant award of approximately \$300,000 to further evaluate SGX943 as a treatment for melioidosis. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. As of December 2015, we had approximately \$43.0 million in active contract funding.

Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through December 2015, we have expended approximately \$66.2 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least \$12.9 million over the next 12 months in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements of which approximately \$7.6 million will be reimbursed through our existing government contracts and grants. Unless and until we are able to generate sales or licensing revenue from 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.

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If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of early 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:

we may not be able to maintain our current research and development schedules;

we may be unable to secure procurement contracts on beneficial economic terms or at all from the U.S. government or others for our biodefense products;

we may encounter problems in clinical trials; or

the technology or product may be found to be ineffective or unsafe, or may fail to obtain marketing approval.

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 be unable to 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 expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a late-stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking clinical studies and clinical trials of our product candidates in our two active business segments, BioTherapeutics and Vaccines/BioDefense. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this prospectus and also include:

our ability to obtain additional funding to develop our product candidates;

delays in the commencement, enrollment and timing of clinical trials;

the success of our product candidates through all phases of clinical development;

any delays in regulatory review and approval of product candidates in clinical development;

our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;

potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;

our dependence on third-party contract manufacturing organizations to supply or manufacture our products;

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our dependence on contract research organizations to conduct our clinical trials;

our ability to establish or maintain collaborations, licensing or other arrangements;

market acceptance of our product candidates;

our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;

competition from existing products or new products that may emerge;

the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;

our ability to discover and develop additional product candidates;

our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;

our ability to attract and retain key personnel to manage our business effectively;

our ability to build our finance infrastructure and improve our accounting systems and controls;

potential product liability claims;

potential liabilities associated with hazardous materials; and

our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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

Our business is subject to very stringent 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.

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 is uncertain as to outcome, and requires the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials.

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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 product recalls and suspension or 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, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government's biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the United States and internationally have the capability to test animals with anthrax or ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.