SOLIGENIX, INC.
Form 424B4
June 29, 2018

PROSPECTUS **Filed Pursuant to Rule 424(b)(4)**

Registration No. 225226

7,766,990 Shares of Common Stock
Warrants to Purchase up to 3,106,796 Shares of Common Stock

We are offering 7,766,990 shares of our common stock and warrants to purchase up to 3,106,796 shares of our common stock pursuant to this prospectus (and the shares of our common stock that are issuable from time to time upon exercise of the warrants). The warrants will have a per share exercise price of $2.25. Each share of our common stock is being sold in this offering together with a warrant that will have the right to purchase 0.4 of a share of our common stock. The shares of our common stock and the warrants will be separately issued. The warrants are exercisable immediately and will expire forty-two months from the date of issuance.

Our common stock and our common stock warrant issued in connection with our December 2016 public offering are traded on The Nasdaq Capital Market under the symbols “SNGX” and “SNGXW,” respectively. On June 27, 2018, the last reported sales prices of our common stock and our common stock warrant issued in connection with our 2016 public offering on The Nasdaq Capital Market were $1.03 per share and $0.45 per warrant.

Our business and an investment in our securities involves a high degree of risk. See “Risk Factors” beginning on page 7 of this prospectus for a discussion of information that you should consider before investing in our securities.

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.

	Per Share	Per Warrant	Total
Public offering price	$1.0299	$0.0001	$7,999,999.70

Discounts and commissions to underwriters	$0.0533(1)	$0.000007	$413,964.61
Offering proceeds to us, before expenses	$0.9766	$0.000093	$7,586,035.09

(1) Represents a weighted average of the compensation to be received by the underwriters. The underwriters will receive compensation in addition to the underwriting discount. See "Underwriting" beginning on page 77 of this prospectus for a description of compensation payable to the underwriters.

Altamont Pharmaceutical Holdings LLC and its affiliates, and certain of our existing stockholders indicated an interest in purchasing shares of common stock and warrants in this offering at the public offering price. See "Underwriting—Discount, Commissions and Expenses" on page 77 of this prospectus for more information about the investment in this offering by these investors.

We have granted a 45-day option to the representative of the underwriters to purchase up to 1,165,048 additional shares of common stock and/or additional warrants to purchase up to 466,019 shares of common stock from us solely to cover over-allotments, if any.

The underwriters expect to deliver the shares and warrants against payment therefor on or about July 2, 2018.

A.G.P.

June 27, 2018

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, especially the "Risk Factors" section of this prospectus and the financial statements and related notes appearing at the end of this prospectus before making an investment decision. 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 novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

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 therapeutic candidate for antibiotic resistant and emerging infectious disease. 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 have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID.

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;

Continue enrollment of our pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer, including the expansion of the Phase 3 trial of SGX942 to select European study sites;

Continue development of RiVax® in combination with our ThermoVax® technology to develop a new heat stable vaccine in biodefense with NIAID funding support;

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

Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and

Acquire or in-license new clinical-stage compounds for development.

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Our Product Candidates in Development

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 December 2015, with an interim analysis anticipated in the second half of 2018 and final results expected in the first half of 2019
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial initiated July 2017, with interim analysis anticipated in the first half of 2019 and final results expected in the second half of 2019
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial initiation contingent upon additional funding, such as through partnership
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial completed; safety profile and preliminary efficacy demonstrated

Vaccine Thermostability Platform**

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

BioDefense Products**

Soligenix Product Candidate	Indication	Stage of Development
RiVax®	Vaccine against	Phase 1a and 1b trials completed, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the second

	Ricin Toxin Poisoning	half of 2018
OrbeShield®	Therapeutic against GI ARS	Pre-clinical
SGX943	Therapeutic against Emerging Infectious Disease	Pre-clinical

** Contingent upon continued government contract/grant funding or other funding source.

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The Offering

Securities offered by us	7,766,990 shares of our common stock and warrants to purchase up to 3,106,796 shares of common stock.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 1,165,048 additional shares of our common stock and/or additional warrants to purchase up to 466,019 shares of our common stock from us at the public offering price less underwriting discounts and commissions.
Description of the warrants	Each share of our common stock is being sold in this offering together with a warrant to purchase 0.40 of a share of our common stock. Each warrant will have an exercise price per share of $2.25 (subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events). No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will round up or down, as applicable, to the nearest whole number. The warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume our obligations under the warrants. In addition, the holder of the warrant will be entitled to receive upon exercise of the warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the warrant immediately prior to such fundamental transaction. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. The warrants are exercisable immediately and expire forty-two months from the date of issuance.
Representative's warrants	We will issue to Alliance Global Partners ("A.G.P."), the representative of the underwriters, upon closing of this offering, compensation warrants entitling A.G.P. or its designees to purchase 2.0% of the aggregate number of the shares of common stock that we issue in this offering (excluding any shares issued upon exercise of the underwriters' over-allotment option). The representative's warrants will be exercisable for no more than forty-two months from the effective date of this offering and may be exercised commencing 12 months after the date of effectiveness of the registration statement of which this prospectus forms a part. The representative's warrants may be exercised on a cashless basis.
Common stock outstanding after this offering	16,517,791 shares of common stock, assuming none of the warrants offered hereby are exercised (19,624,587 if the warrants offered hereby are exercised in full). If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 17,682,839 assuming none of the warrants offered hereby are exercised (21,255,654 if the warrants offered hereby are exercised in full). This prospectus also includes the shares of our common stock issuable upon exercise of the warrants.

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Use of proceeds	We estimate that the net proceeds from our sale of our securities in this offering will be approximately $7.3 million, or approximately $8.5 million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds received from this offering to fund our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and our pivotal Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients, as well as for general working capital purposes. See "Use of Proceeds" on page 28.
Risk Factors	See the section titled "Risk Factors" beginning on page 7 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.
Nasdaq Capital Market symbol	Our common stock and our common stock warrant issued in connection with our December 2016 public offering are listed on The Nasdaq Capital Market under the symbols "SNGX" and "SNGXW," respectively. We do not intend to apply for listing of the warrants offered hereby on any securities exchange or other trading market, and we do not expect that a public trading market will develop for the warrants. Without an active trading market, the liquidity of the warrants will be limited.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 8,750,801 shares of common stock outstanding as of June 27, 2018, after giving effect to the issuance of 7,766,990 shares of our common stock in this offering at $1.0299 per share.

Unless we indicate otherwise, all information in this prospectus:

- reflects a one-for-ten reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on October 7, 2016 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share;
- is based on 8,750,801 shares of common stock issued and outstanding as of June 27, 2018;
- assumes no exercise by the underwriters of their option to purchase up to an additional 1,165,048 shares of common stock and/or warrants to purchase up to 466,019 shares of common stock to cover over-allotments, if any;
- excludes 155,340 shares of our common stock underlying warrants to be issued to the representative of the underwriters in connection with this offering;
- excludes 3,106,796 shares of our common stock underlying warrants to be issued in this offering;

excludes 2,575,988 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of $4.38 per share as of June 27, 2018;

excludes 761,855 shares of our common stock issuable upon exercise of outstanding stock options under our equity compensation plans at a weighted average exercise price of $7.25 per share as of June 27, 2018; and

excludes 36,469 shares of our common stock that are reserved for equity awards that may be granted under our existing equity incentive plans.

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 B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

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SUMMARY FINANCIAL DATA

The following table sets forth our summary statement of operations data for the fiscal years ended December 31, 2017 and 2016 derived from our audited financial statements and related notes included elsewhere in this prospectus. The summary financial data for the three months ended March 31, 2018 and 2017, and as of March 31, 2018, are derived from our unaudited financial statements appearing elsewhere in this prospectus and are not indicative of results to be expected for the full year. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled “Capitalization,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	Three Months Ended March 31,		Year Ended December 31,	
	2018	2017	2017	2016
Revenues				
Contract revenue	$777,284	$1,330,884	$4,749,294	$10,448,794
Grant revenue	342,489	-	683,178	-
Total revenues	1,119,773	1,330,884	5,432,472	10,448,794
Cost of revenues	(978,921)	(1,087,315)	(4,310,083)	(8,433,671)
Gross profit	140,852	243,569	1,122,389	2,015,123
Operating expenses:				
Research and development	1,803,360	1,217,540	5,507,033	4,295,867
General and administrative	731,593	764,219	3,209,155	3,428,838
Total operating expenses	2,534,953	1,981,759	8,716,188	7,724,705
Loss from operations	(2,394,101)	(1,738,190)	(7,593,799)	(5,709,582)
Other income (expense):				
Change in fair value of warrant liability	—	—	—	1,541,241
Gain on settlement liability	—	—	—	390,599
Interest income, net of expense	16,895	4,753	29,906	2,216
Total other income (expense)	16,895	4,753	29,906	1,934,056
Net loss before income taxes	—	—	(7,563,893)	(3,775,526)
Income tax benefit	—	—	416,810	530,143
Net loss	$(2,377,206)	$(1,733,437)	$(7,147,083)	$(3,245,383)
Basic net loss per share	$(0.27)	$(0.32)	$(1.16)	$(0.93)
Diluted net loss per share	$(0.27)	$(0.32)	$(1.16)	$(1.34)
Basic weighted average common shares outstanding	8,734,897	5,472,449	6,144,237	3,481,460
Diluted weighted average common shares outstanding	8,734,897	5,472,449	6,144,237	3,583,587

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	As of March 31, 2018	
	Actual	**Pro Forma, As Adjusted[(1)]**
Balance Sheet Data:		
Cash and cash equivalents	$6,368,057	13,725,657
Total assets	$7,478,799	14,836,399
Total liabilities	$3,408,523	3,408,523
Total shareholders' equity	$4,070,276	11,427,876

(1) Pro forma, as adjusted amounts give effect to (i) the issuance of 10,078 shares of common stock for which we received $18,600 from April 1, 2018 through and immediately prior to the date of this prospectus, and (ii) the sale of 7,766,990 shares in this offering at the public offering price of $1.0299 per share and warrants at the public offering price of $0.0001 per warrant, and after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

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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 March 31, 2018, had an accumulated deficit of approximately $160 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2018, we had approximately $6.4 million in cash and cash equivalents 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 line, we expect to be able to maintain the current level of our operations for at least the next twelve months.

In September 2014, we entered into a contract with the National Institutes of Health ("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 over six years if options to extend the contract are exercised by the NIH. In September 2013, we entered into contracts with NIAID 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. We have received approximately $18 million in combined BARDA and NIH contract funding for the development of OrbeShield®. We have completed the contract with NIAID and the BARDA contract base period, with BARDA electing not to extend the contract. In addition, in 2017, we were awarded two separate grants from the NIH of approximately $1.5 million each to support our pivotal Phase 3 trials of SGX301 for the treatment of CTCL and SGX942 for the treatment of oral mucositis in head and neck cancer. 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. We have approximately $18.4 million in awarded contract and grant funding, assuming the NIAID options are exercised for the development of RiVax®. BARDA has elected not to fund the

additional options remaining under the contract for the development of OrbeShield®.

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 March 31, 2018, we have expended approximately $77.8 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend approximately $11.5 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 $5.9 million is expected to be reimbursed through our existing government contracts and grants.

We have no control over the resources and funding NIH, BARDA and NIAID may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIH, BARDA or NIAID do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results.

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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.

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.

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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 pre-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;

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.

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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 contracts and 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 U.S. Food and Drug Administration (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.

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.

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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 countermeasures 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 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.

We are 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 receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that

we will receive or continue to receive funding for grants and contracts we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

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 anticipate 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 be able to develop, produce, secure regulatory approval of 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.

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We rely on third parties for pre-clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We rely on academic institutions, hospitals, clinics and other third-party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and/or oversee our pre-clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and/or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

The manufacturing 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 may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved New Drug Application ("NDA") is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

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Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any product that we develop will depend on a number of factors, including:

cost-effectiveness;

the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods;

the timing of market entry as compared to competitive products;

the rate of adoption of our products by doctors and nurses;

product labeling or product insert required by the FDA for each of our products;

reimbursement policies of government and third-party payors;

effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and

unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

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

We do not have extensive experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to successfully market and sell any of our products, the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships will be required. 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.

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If any of our product candidates cause serious adverse events or undesirable side effects:

regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;

we may be required to limit the patients who can receive the product;

we may be subject to limitations on how we promote the product;

sales of the product may decrease significantly;

regulatory authorities may require us to take our approved product off the market;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

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If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for SGX301 in the United States and Europe, and SGX203, RiVax® and OrbeShield® in the United States, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or European Medicines Agency may subsequently approve the same drug with the same active moiety for the same condition if the FDA or European Medicines Agency concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

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

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

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that were separately billed at that time. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment.

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

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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 New York University, Yeda Research and Development Company Ltd., the University of Texas Southwestern Medical Center, the University of British Columbia, Harvard University, the University of Colorado (the "UC"), 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, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

In April 2018, the UC delivered a notice of termination of our license agreement for heat stabilization technology based upon our failure to achieve one of the development milestones: initiation of the Phase 1 clinical trial of the heat stabilization technology by March 31, 2018. After negotiating with the UC regarding termination, we and the UC have agreed to extend the termination date to October 31, 2018 in order to allow us time to attempt to agree upon terms of a potential agreement, which would allow us to keep the rights to, and to continue to develop, the heat stabilization technology or a product candidate containing the heat stabilization technology. Currently, no terms have been agreed upon and we cannot assure that our efforts to retain our rights to the heat stabilization technology will proceed on a timely basis, or at all. If we are unable to successfully retain our rights to the heat stabilization technology our development of the heat stabilization technology may cease and our development of RiVax® may be delayed, which could harm our business, prospects, financial condition and results of operations.

Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See "Business - Patents and Other Proprietary Rights" for a description of our license agreements.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

the scope of rights granted under the license agreement and other interpretation-related issues;

the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

the sublicensing of patent and other rights;

our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and

the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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 or enter into commercialization agreements with other companies. 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 $10 million, which

may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

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We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may not be able to compete with our larger and better financed 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 with our existing and future competitors, which could lead to the failure of our business.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See “Business - The Drug Approval Process.”

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

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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 17 employees and we depend upon these employees, in particular Dr. Christopher Schaber, our President and Chief Executive Officer, 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 may be unable to effectively manage and operate our business, and our business may suffer, if we lose the services of our employees.

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 years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the 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 current and future economic conditions. 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.

We may not be able to utilize all of our net operating loss carryforwards.

The State of New Jersey’s Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss (“NOL”) carryforwards to other New Jersey-based corporate taxpayers. In accordance with this program, during the year ended December 31, 2017, we sold New Jersey NOL carryforwards, resulting in the recognition of $416,810 of income tax benefit. If there is an unfavorable change in the State of New Jersey’s Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our NOL carryforwards, our cash taxes may increase which may have an adverse effect on our financial condition.

Risks Related to our Intellectual Property

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 near and long-term prospects depend 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 own or license, now or 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 (the “PTO”) regarding the breadth of claims allowed in biotechnology patents.

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In addition, because patent applications in the U.S. are maintained in secrecy until patent applications publish or 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 PTO 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 owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable 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.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an

infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to our Securities and this Offering

The price of our common stock and warrants may be highly volatile.

The market price of our securities, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and the price of our common stock and warrants may be volatile 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;

failure of our common stock or warrants to continue to be listed or quoted on a national exchange or market system, such as The NASDAQ Stock Market (“NASDAQ”) or NYSE Amex LLC;

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;

general market conditions.

Since January 1, 2017, the closing stock price of our common stock has fluctuated between a high of $5.08 per share to a low of $1.03 per share. Since January 1, 2017, the closing price of our common stock warrants has fluctuated between a high of $1.31 per warrant to a low of $0.17 per warrant. On June 27, 2018 the last reported sales prices of our common stock and our common stock warrant on The Nasdaq Capital Market were $1.03 per share and $0.45 per warrant. The fluctuation in the price of our common stock and warrants has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock and warrants by us, as well as potential 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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The outstanding warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, the holders of the outstanding warrants may exercise their right to acquire the common stock and pay the per share exercise price, prior to the expiration date, after which date any unexercised warrants will expire and have no further value.

Holders of the warrants offered hereby will have no voting rights as common stockholders until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the warrants, you will have no rights with respect to our common stock issuable upon exercise of the warrants. Upon exercise of your warrants, you will be entitled to exercise all the voting rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Significant holders or beneficial holders of our common stock may not be permitted to exercise warrants that they hold.

The warrants offered hereby will prohibit a holder from exercising its warrants if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 4.99% of our common stock outstanding immediately after giving effect to the exercise. As a result, you may not be able to exercise your warrants for shares of our common stock at a time when it would be financially beneficial for you to do so. In such circumstance you could seek to sell your warrants to realize value, but you may be unable to do so.

The warrants offered hereby are speculative in nature.

The warrants offered hereby do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $2.25 per share, prior to forty-two months from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, the Company has no plans to apply to have the warrants listed on any exchange and no assurance can be given that a market for the warrants will develop. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

The warrants hereby offered may not have any value.

Each warrant will have an exercise price of $2.25 per share and will expire 42 months from the original issuance date. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

Investors will experience immediate and substantial dilution as a result of this offering and may suffer substantial dilution related to issued stock warrants and options.

Investors will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to 7,766,990 shares of common stock and warrants to purchase up to an aggregate of 3,106,796 shares of common stock offered in this offering at the public offering price of $1.0299 per share and $0.0001 per warrant, and after deducting the underwriters' discount and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $0.34 per share, without giving effect to the potential exercise of the warrants offered hereby.

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In addition, as of March 31, 2018, we had a number of agreements or obligations that may result in dilution to investors. These include:

warrants to purchase up to a total of approximately 2,577,238 shares of our common stock at a current weighted average exercise price of approximately $4.38; and

options to purchase approximately 782,155 shares of our common stock at a current weighted average exercise price of approximately $7.16.

We also have an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants. To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

Additionally, the sale, or even the possibility of the sale, of the shares of common stock underlying these warrants and options could have an adverse effect on the market price for our securities or on our ability to obtain future financing.

Anti-takeover provisions in our corporate governance documents and under Delaware law could make a third party acquisition of the Company difficult.

Provisions in our Certificate of Incorporation and by-laws may discourage certain types of transactions involving an actual or potential change of control of our company which might be beneficial to us or our security holders. We also are subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

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

Our common stock and warrants have from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock or warrants 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 and warrants will develop or be sustained, or that current trading levels will be sustained.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, our stockholders must rely on sales of their common stock and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock or warrants will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Upon dissolution of the Company, our stockholders may not recoup all or any portion of their investment.

In the event of a liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the proceeds and/or assets of the Company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the holders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of the Company. In this event, our stockholders could lose some or all of their investment.

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The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 22, 2016, we entered into a purchase agreement (the "2016 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the 2016 Purchase Agreement, Lincoln Park has committed to purchase up to $12 million of our common stock, of which approximately $10.1 million worth of our common stock remains issuable as of the date of this prospectus. Concurrently with the execution of the 2016 Purchase Agreement, we issued 10,000 shares of our common stock to Lincoln Park as a partial fee for its commitment to purchase shares of our common stock under the 2016 Purchase Agreement. From March 22, 2016 through the date of this prospectus, we sold 330,000 shares to Lincoln Park and issued 7,778 additional shares to Lincoln Park as additional commitment shares under the 2016 Purchase Agreement and received proceeds of $1,866,650. The shares that may be sold pursuant to the 2016 Purchase Agreement may be sold by us to Lincoln Park at our sole discretion from time to time over the remaining term of approximately 10 months from the date of this prospectus, provided the registration statement registering the resale of shares sold to Lincoln Park under the 2016 Purchase Agreement remains effective. The purchase price for the shares that we may sell to Lincoln Park under the 2016 Purchase Agreement will fluctuate based on the price of our common stock. We have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park that would cause Lincoln Park to beneficially own more than 4.99% of our issued and outstanding common stock.

Depending on market liquidity at the time, sales of shares under the 2016 Purchase Agreement may cause the trading price of our common stock to fall. Additionally, further sales of our common stock, if any, to Lincoln Park under the 2016 Purchase Agreement will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the 2016 Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the 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.

The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall.

On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma Inc. ("Hy Biopharma") granted us an option to purchase certain assets, properties and rights (the "Hypericin Assets") related to the development of Hy Biopharma's synthetic hypericin product candidate for the treatment of CTCL, which we refer to as SGX301, from Hy Biopharma. In exchange for the option, we paid $50,000 in cash and issued 4,307 shares of common stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we

entered into an asset purchase agreement with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the purchase agreement, we paid $275,000 in cash and issued 184,912 shares of common stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma, and may issue up to an aggregate of $10 million worth of our common stock (subject to a cap equal to 19.99% of our issued and outstanding common stock) in the aggregate upon attainment of specified milestones. The next milestone payment will be payable if the Phase 3 clinical trial of SGX301 is successful in demonstrating efficacy and safety in the CTCL patient population. Also on September 3, 2014, we entered into a Registration Rights Agreement with Hy Biopharma, pursuant to which we have filed a registration statement with the SEC.

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The number of shares that we may issue under the purchase agreement will fluctuate based on the market price of our common stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our common stock to fall.

We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the purchase agreement. We are required to register any shares issued pursuant to the purchase agreement for resale under the Securities Act of 1933, as amended (the "Securities Act"). After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the purchase agreement, or the anticipation of such issuances, 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.

Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.

We currently intend to use the net proceeds from this offering to fund our research and development activities and for working capital and general corporate purposes (see "Use of Proceeds"). We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, and results of operation.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA AND MARKET INFORMATION

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are often identified by words such as "may," "should," "would," "expect," "intend," "anticipate," "believe," "estima "continue," "plan," "potential" and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

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

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

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