SOLIGENIX, INC.
Form S-1/A
March 01, 2013

As filed with the Securities and Exchange Commission on March 1, 2013.

Registration No. 333-184762

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1
TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	2834	41-1505029
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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

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

Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
Soligenix, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

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

with copies to:

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(212) 370-1300

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered		Proposed maximum aggregate offering price		Amount of registration fee(1)
Units, each unit consisting of one share of Common Stock, $0.001 par value, and a warrant to purchase up to an additional _____ share of Common Stock	$	10,000,000	$	1,346
Common Stock included in the units	$	—	$	—
Warrants included in the units	$	—		(3)
Common Stock issuable upon exercise of the warrants included in the units (2)	$	—		(3)
Series A Junior Participating Preferred Stock Purchase Rights (4)				
Total	$	10,000,000	$	1,364 (5)

_____

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(3) No fee required pursuant to Rule 457(g).

(4) This registration statement also covers the Preferred Share Purchase Rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between the Registrant and American Stock Transfer & Trust Company, as Rights Agent, which are presently attached to and trade with the Registrant’s common stock.

(5) The registrant previously paid $955 of the registration fee in connection with the filing of its Form S-1 Registration Statement filed with the Securities and Exchange Commission on November 5, 2012.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED MARCH 1, 2013

SOLIGENIX, INC.

UP TO _____ UNITS, EACH CONSISTING OF ONE SHARE OF COMMON STOCK AND WARRANTS TO PURCHASE UP TO AN ADDITIONAL _____ SHARE OF COMMON STOCK

We are offering up to _____ units on a "best efforts" basis, with each unit consisting of one share of our common stock, a warrant to purchase up to an additional _____ share of our common stock, together with the associated preferred stock purchase rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company, which are attached to and trade with our common stock. The warrants entitle holders to purchase _____ share of our common stock for each warrants they hold at a price equal to _____% of the price of each unit. The units will separate immediately and the common stock and warrants will be issued separately will trade separately; however until exercised the preferred stock purchase rights will trade with the shares of common stock to which such rights are presently attached. We are not required to sell any specific dollar amount or number of units. We and the placement agents may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

Our common stock is listed on the OTCQB market under the symbol "SNGX". We do not intend to apply for listing of the warrants on any securities exchange. On February 25, 2013, the last quoted sale price of our common stock as reported on the OTCQB was $1.79 per share.

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

	Per unit	Total
Offering Price	$_____	$_____
Placement Agent's Fees	$_____	$_____
Placement Agent's Fees (officers, directors and company investors)	$_____	$_____
Offering Proceeds before expenses	$_____	$_____

Maxim Group LLC and Brean Capital, LLC have agreed to act as our co-lead managing placement agents in connection with this offering. In addition, we or the placement agents may engage one or more sub placement agents or selected dealers. The placement agents are not purchasing the securities offered by us, and are not required to sell any specific number or dollar amount of units, but will assist us in this offering on a "best efforts" basis. We have agreed to pay the placement agents a cash fee equal to (i) 8% of the gross proceeds received by investors who purchase units in the offering that are contacted by the placement agents, (ii) 4% of the gross proceeds received from our officers or directors (in excess of the first $300,000 of gross proceeds received from such officers and directors) or from certain investors with which we have a previous relationship and (iii) $25,000 upon the execution of the engagement letter with the placement agents. Additionally, we have agreed to issue the placement agents "placement agent warrants" to purchase shares of our common stock equal to 5% of the aggregate number of shares of common

stock included in units sold in the offering (excluding shares sold to our officers or directors). The placement agent warrants will have terms substantially similar to the warrants included in units offered hereby but provide for a cashless exercise feature. We estimate the total expenses of this offering, excluding the placement agents' fees, will be approximately $_____. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See "Plan of Distribution" beginning on page 51 of this prospectus for more information on this offering and the placement agents arrangements.

The offering expires on the earlier of (i) the date upon which all of the units being offered have been sold, or (ii) _____, 2013. We may decide to terminate the offering at any time without further notice to investors. All costs associated with the registration will be borne by us. Pursuant to an escrow agreement among us, the placement agents and _____, as escrow agent, some or all of the funds received in payment for the units sold in this offering will be wired to a non-interest bearing escrow account and held until we and the placement agents notify the escrow agent that this offering has closed.

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

Co-lead managing placement agents

Maxim Group LLC Brean Capital, LLC

The date of this prospectus is _____, 2013

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

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

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements. These forward-looking statements are often identified by words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "continue," "plan," “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;

significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;

our ability to obtain regulatory approvals;

uncertainty as to whether our technologies will be safe and effective;

our ability to obtain future financing or funds when needed;

that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;

our ability to obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;

our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;

our ability to patent, register and protect our technology from challenge and our products from competition;

maintenance or expansion of our license agreements with our current licensors;

changes in healthcare regulation;

changes in the needs of biodefense procurement agencies;

maintenance and progression of our business strategy;

the possibility that our products under development may not gain market acceptance; and

that others may develop technologies or products superior to our products.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All

subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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PROSPECTUS SUMMARY

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

About Our Company

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (or BDP) for the prevention/treatment of gastrointestinal (or GI) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (or IDR) technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (or GI ARS) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

An outline for our business strategy follows:

Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease (or GVHD);

Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

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

Explore other business development and merger/acquisition strategies.

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

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial planned for the first half of 2013, with data expected in the first half of 2013
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the first half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

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

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the first half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; protection observed in canines

Recent Developments

The following are certain recent developments:

On February 20, 2013, we announced the submission of a full contract proposal to the Biomedical Advanced Research and Development Authority's Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures. This submission supports a potential multi-year, multi-million dollar contract to develop OrbeShield™ as a medical countermeasure (MCM) for the treatment of GI ARS.

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On January 29, 2013, we announced that our OrbeShield™ development program for the treatment of GI ARS received "Fast Track" designation from the U.S. Food and Drug Administration (“FDA”).

On January 4, 2013, we announced that the FDA completed its review and cleared our IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS.

On January 2, 2013, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to OrbeShield™ for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

On December 28, 2012, we announced that we received approximately $521,000, net of transaction costs, in non-dilutive financing via the State of New Jersey's Technology Business Tax Certificate Transfer Program.

On December 27, 2012, we announced that we regained the North American and European commercial rights to oral BDP through an amendment of our Collaboration and Supply Agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”). We are now free to commercialize or enter into commercialization agreements for our oral BDP suite of products with other parties without limitation.

On December 18, 2012, we announced the acquisition of a novel drug technology, referred to as SGX94, representing a novel approach to modulation of the innate immune system. As part of the acquisition, we acquired all rights to SGX94, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94, which is poised to enter Phase 2 clinical testing in humans.

Corporate Information

We were incorporated in Delaware in 1987 under the name Immunotherapeutics Inc. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

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Summary of the Offering

Securities Offered	Up to _____ units. Each unit will consist of one share of our common stock, a warrant to purchase up to an additional _____ shares of our common stock, together with the associated preferred stock purchase rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company, which are attached to and trade with our common stock. Units may be issued and sold in one or more closings up to the termination date, _____, 2013.
Offering Price	$_____ per unit.
Description of Warrants	The warrants will be exercisable at any time during the period commencing after the date of closing and ending on the fifth anniversary of the closing date at an exercise price per share equal to _____% of the price of each unit. We and the placement agents may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.
Common Stock Outstanding Prior to the Offering	_____ shares.
Common Stock Outstanding After the Offering	_____ shares, which does not include _____ shares of common stock issuable upon exercise of the warrants included in the offered units.
Use of Proceeds	We expect to use the proceeds received from the offering to further develop our products and product candidates and for general working capital purposes.
OTCQB Symbol	SNGX
Risk Factors	See “Risk Factors” beginning on page 6 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the units.

The total number of shares of our common stock outstanding as of the date of this prospectus was 11,179,968, which excludes the following:

129,711 shares of common stock reserved for future issuance under our equity incentive plans. As of the date of this prospectus, there were options to purchase 1,457,724 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $3.19 per share;

2,843,338 shares of common stock issuable upon exercise of outstanding warrants as of the date of this prospectus

with a weighted average exercise price of $3.13 per share; and

_____ shares of common stock that will be issuable upon exercise of warrants at an exercise price of $_____ per share sold as part of the units in this offering.

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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 have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2012, we have approximately $3.4 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years, we expect to be able to maintain the current level of our operations into the second quarter of 2014.

We have sufficient funds through our existing biodefense grant facilities from the NIAID, a division of the NIH, to finance our biodefense projects for the next several years. In September 2009, we received a NIAID grant for approximately $9.4 million for the development of our biodefense programs and recently received an additional SBIR grant from NIAD for $600,000. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs.

Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through December 2012, we have expended approximately $46.7 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $3 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from 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, manufacture 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;

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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.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be 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.

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. For example, our confirmatory Phase 3 clinical trial for orBec® (oral BDP) in the treatment of GI GVHD was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board (“DSMB”) as it was highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Although no safety concerns were raised by the DSMB, preliminary findings indicated that there were no significant differences between the orBec® group and placebo group for the primary endpoint or for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, we terminated the development of orBec® for the treatment of acute GI GVHD. Although we hope to obtain FDA approval for oral BDP in similar indications, such as treatment of chronic GI GVHD, treatment of pediatric Crohn's disease, acute radiation enteritis, and GI ARS, there can be no assurances that the FDA will ever approve oral BDP for market launch in any of these indications.

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.

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

There may be unforeseen challenges in developing our biodefense products.

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

We will be dependent on government funding, which is inherently uncertain, in order to progress 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 other governmental agencies, the viability 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 documents and other regulations.

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or

manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to 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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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 cGMP or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We do not have sales and marketing experience and our lack of experience may restrict our ability to commercialize some of our product candidates.

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to 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.

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 commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

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

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

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates

addressing small patient populations.

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

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

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

We currently rely on license agreements from the University of Texas Southwestern Medical Center, the University of British Columbia, Harvard University, the University of Colorado, and George B. McDonald, MD for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are 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 $5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain,

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

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We may not be able to compete 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 and hinder us from securing procurement contracts with the government. 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.

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

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

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

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

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply

technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

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

We currently have only 10 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 months, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment and the potential impact of the so-called “fiscal cliff” arising from the combination of tax increases and automatic spending cuts scheduled to take effect at the end of calendar 2012 and in early calendar 2013 in the U.S. 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.

Risks Related to Our Common Stock

Our common stock price is highly volatile.

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

announcements by us or others of results of pre-clinical testing and clinical trials;

announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

our quarterly operating results and performance;

developments or disputes concerning patents or other proprietary rights;

acquisitions;

litigation and government proceedings;

adverse legislation;

changes in government regulations;

our available working capital;

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economic and other external factors; and

general market conditions.

Since January 1, 2012, the closing stock price (split adjusted) has fluctuated between a high of $2.05 per share to a low of $0.23 per share. As of February 25, 2013, our common stock closed at $1.79 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of our common stock, 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.

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

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

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

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

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

warrants to purchase a total of approximately 2,843,338 shares of our common stock at a current weighted average exercise price of approximately $3.13; and

options to purchase approximately 1,457,724 shares of our common stock at a current weighted average exercise price of approximately $3.19.

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

Anti-takeover provisions in our stockholder rights plan and under Delaware law could make a third party acquisition of our company difficult.

Our stockholder rights plan contains provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of our company. The rights issued pursuant to our stockholder rights plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of our common stock or commences, or announces an intention to make, a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of our common stock) will be entitled to acquire, in exchange for the rights' exercise price, shares of our common stock or shares of any company in which we are merged, with a value equal to twice the rights' exercise price.

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

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

USE OF PROCEEDS

We estimate that we will receive up to $_____ in net proceeds from the sale of units in this offering, based on an assumed price of $_____ per unit and after deducting estimated placement agents' fees and estimated offering expenses payable by us. We will use the net proceeds from this offering to further develop our products and product candidates and for working capital and other general corporate purposes. We will have broad discretion over the use of proceeds from this offering.

DILUTION

If you purchase units in this offering, and assuming no value is attributed to the warrants, your interest will be diluted immediately to the extent of the difference between the assumed public offering price of $_____ per unit and the as adjusted net tangible book value per share of our common stock immediately following this offering.

Our net tangible book value as of December 31, 2012 was approximatFONT SIZE=1>**2009** **2008**

Audit Fees

$556,500 $557,500

Audit-related Fees

1,500 2,500

Tax Fees

All Other Fees

$558,000 $560,000

Audit Fees

KPMG LLP charged $556,500 and $557,500 in fiscal years 2009 and 2008, respectively, for professional services in connection with the audit of the Company's annual financial statements and its internal control over financial reporting and for the reviews of the Company's financial statements included in the Company's Quarterly and Annual Reports on Form 10-Q and Form 10-K and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for the fiscal years shown.

Audit-related Fees

KPMG LLP charged $1,500 and $2,500 in fiscal years 2009 and 2008, respectively, for professional services related to reviews of specific restaurants' sales for licensing purposes.

Tax Fees

KPMG LLP did not perform any tax consulting services in fiscal years 2009 and 2008.

All Other Fees

KPMG LLP did not bill the Company for any fees for products and services rendered in fiscal years 2009 and 2008 other than those reported in the foregoing paragraphs.

Pre-approval Policies and Procedures

The audit committee pre-approved all audit, audit-related and permissible non-audit services provided to the Company by KPMG LLP before management engaged the auditors for those purposes. The policy of the committee is to review all engagement letters for accounting firms for non-audit services while allowing the Company to enter into the agreements, but to specifically pre-approve all services to be provided by the firm which performs the annual audit of the Company's financial statements and internal control over financial reporting.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The audit committee's charter provides that the audit committee will review and approve any transactions between us and any of our executive officers, directors and 5% stockholders, or any members of their immediate families, in which the amount involved exceeds the threshold limits established by the regulations of the SEC. In reviewing a related-party transaction, the audit committee considers the material terms of the transaction, including whether the terms are generally available to an unaffiliated third party under similar circumstances. Except as specifically noted, the transactions described below were entered into prior to our IPO, and we were contractually obligated to perform under these agreements prior to the formation of the audit committee.

Grants of Franchise or License Rights

We have licensed or franchised restaurants to companies owned in part by the executive officers, directors and 5% stockholders listed below. The licensing or franchise fees paid by these companies to us range from 0.0% to 3.5% of restaurant sales.

Restaurant	Name and Ownership	Initial Franchise Fee	Royalty Rate	Fees Paid to Us in Fiscal 2009 ($ in thousands)
Billings, MT	W. Kent Taylor (55.0%) Scott M. Colosi (2.0%)		3.5%	149.8
Bossier City, LA	Steven L. Ortiz (66.0%)		3.5%	144.1
Brownsville, TX	G.J. Hart (61.23%) Steven L. Ortiz (30.61%)		3.5%	158.9
Everett, MA	W. Kent Taylor (59.0%)		3.5%	205.8
Fargo, ND	G.J. Hart (83.84%) Scott M. Colosi (5.05%)		3.5%	142.7
Longmont, CO	Steven L. Ortiz (47.5%)		3.5%	110.9
McKinney, TX	G.J. Hart (30.0%) Steven L. Ortiz (30.0%) Scott M. Colosi (2.0%)		3.5%	138.9
Melbourne, FL(1)	W. Kent Taylor (34.0%)			90.0
Muncie, IN(2)	W. Kent Taylor (11.48%)		$50,000 per year	50.0
New Berlin, WI	G.J. Hart (30.0%) Steven L. Ortiz (30.0%) Scott M. Colosi (2.0%)		3.5%	102.4
Omaha, NE	G.J. Hart (68.68%) Scott M. Colosi (10.99%)		3.5%	156.6
Port Arthur, TX	W. Kent Taylor (30.0%) G.J. Hart (30.0%) Steven L. Ortiz (30.5%) Scott M. Colosi (3.0%)		3.5%	179.8
Temple, TX	Steven L. Ortiz (78.0%)		3.5%	121.5
Wichita, KS	W. Kent Taylor (51.1%) Scott M. Colosi (4.0%)		3.5%	227.6

(1) Licensed restaurant which opened in September 1996. In lieu of royalties, the entity pays supervision fees.

(2) Licensed restaurant which opened in November 1996.

We have entered into a preliminary franchise agreement with a company which is 95% owned by W. Kent Taylor to develop a restaurant at a location which is to be determined. The terms of the

preliminary franchise agreement provide for no initial franchise fees and royalties of 3.5% of restaurant sales. During 2009, we received no payment from this franchise restaurant, as none was due. The executive officers will not be granted any additional franchise rights.

The franchise agreements and preliminary franchise agreements that we have entered into with our executive officers, directors and 5% stockholders contain the same terms and conditions as those agreements that we enter into with our other franchisees, with the exception of the initial franchise fees and the royalty rates, which are currently $40,000 and 4.0%, respectively, for our other franchisees. With the exception of the Melbourne, FL and Muncie, IN licensed restaurants, we have the contractual right, but not the obligation, to acquire the restaurants owned by our executive officers, directors and 5% stockholders based on a pre-determined valuation formula which is the same as the formula contained in the franchise agreements that we have entered into with other franchisees with whom we have such rights. A preliminary agreement for a franchise may be terminated if the franchisee does not identify and obtain our approval of its restaurant management personnel, locate and obtain our approval of a suitable site for the restaurant or does not demonstrate to us that it has secured necessary capital and financing to develop the restaurant. Once a franchise agreement has been entered into, it may be terminated if the franchisee defaults in the performance of any of its obligations under the agreement, including its obligations to operate the restaurant in strict accordance with our standards and specifications. A franchise agreement may also be terminated if a franchisee dies, becomes disabled or becomes insolvent, fails to make its required payments, creates a threat to the public health or safety, ceases to operate the restaurant or misuses the Texas Roadhouse trademarks.

Other Related Transactions

The Longview, Texas restaurant, which was acquired by us in connection with the completion of our IPO, leases the land and restaurant building from an entity controlled by Steven L. Ortiz, our Chief Operating Officer. The lease is for 15 years and will terminate in November 2014. The lease can be renewed for two additional periods of five years each. Rent is approximately $18,650 per month. The lease can be terminated if the tenant fails to pay the rent on a timely basis, fails to maintain the insurance specified in the lease, fails to maintain the building or property or becomes insolvent. Total rent payments for 2009 were approximately $200,000.

The Bossier City, Louisiana restaurant, of which Steven L. Ortiz beneficially owns 66.0% and we own 5.0%, is leased from an entity owned by Mr. Ortiz. The lease is for 15 years and will terminate on March 31, 2020. The lease can be renewed for three additional periods of five years each. Rent is approximately $15,100 per month for the first five years of the lease and escalates 10% each five years during the term. The lease can be terminated if the tenant fails to pay rent on a timely basis, fails to maintain insurance, abandons the property or becomes insolvent. The tenant's obligation to pay rent commenced in April 2005 and total rent payments for 2009 were approximately $181,000. The audit committee ratified this transaction in February 2005 after considering market rentals of comparable land and building leases and considering our limited ownership interest. Additionally, the audit committee requested that we attempt to purchase the land and building from Mr. Ortiz' entity in the event the restaurant is ever acquired by us.

We entered into real estate lease agreements for franchise restaurants located in Everett, MA, of which W. Kent Taylor beneficially owns 59.0%, Longmont, CO, of which Steven L. Ortiz owns 47.5%, and Fargo, ND, of which G.J. Hart owns 83.84% and Scott M. Colosi owns 5.05%, before our granting franchise rights for those restaurants. We have subsequently assigned the leases to the franchisees, but we remain contingently liable if a franchisee defaults under the terms of a lease. The Longmont lease expires in May 2014, the Everett lease expires in February 2018 and the Fargo lease expires in July 2016.

STOCKHOLDER PROPOSALS

Under Rule 14a-8 promulgated under the Securities Exchange Act of 1934 ("Exchange Act"), stockholders may present proposals to be included in the Company proxy statement for consideration at the next annual meeting of its stockholders by submitting their proposals to the Company in a timely manner. Any such proposal must comply with Rule 14a-8.

The Company's by-laws, copies of which are available from the Company's Corporate Secretary, require stockholders who intend to propose business for consideration by stockholders at the 2011 Annual Meeting, other than stockholder proposals that are included in the proxy statement, to deliver written notice to the principal executive offices of the Company on or before December 10, 2010. This notice must include a description of the business desired to be brought before the annual meeting, the name and address of the stockholder proposing such business and of the beneficial owner, if any, on whose behalf the business is being brought, the class, series and number of shares of the Company which are beneficially owned by the stockholder and such other beneficial owner and any material interest of the stockholder and such other beneficial owner in such business. Similar requirements are set forth in the Company's by-laws with respect to stockholders desiring to nominate candidates for election as director. Exchange Act rules permit management to vote proxies in its discretion in certain cases if the stockholder does not comply with these deadlines, and in certain other cases notwithstanding the stockholder's compliance with these deadlines. If a stockholder submitting a matter to be raised at the Company's next annual meeting or a candidate for election as director desires that such matter or candidate be included in the Company's proxy statement, such matter or candidate must be submitted to the Company no later than December 10, 2010.

The rules of the SEC set forth standards for what stockholder proposals the Company is required to include in a proxy statement for an annual meeting.

STOCKHOLDERS' COMMUNICATIONS WITH THE BOARD

Stockholders that want to communicate in writing with the Board, or specified directors individually, may send proposed communications to the Company's Corporate Secretary, Sheila C. Brown, at 6040 Dutchmans Lane, Suite 200, Louisville, Kentucky 40205. The proposed communication will be reviewed by the audit committee and the General Counsel. If the communication is appropriate and serves to advance or improve the Company or its performance, contains no objectionable material or language, is not unreasonable in length, and is directly applicable to the business of the Company, it is expected that the communication will receive favorable consideration for presentation to the Board or appropriate director(s).

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company's directors and officers, and persons who beneficially own more than 10% of a registered class of the Company's equity securities, to file with the SEC initial reports of stock ownership and reports of changes in stock ownership and to provide the Company with copies of all such filed forms. Based solely on its review of such copies or written representations from reporting persons, the Company believes that all reports were filed on a timely basis during the fiscal year ended December 29, 2009.

FORM 10-K

The Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2009, accompanies this proxy statement. The Company's Annual Report does not form any part of the material for solicitation of proxies.

Any stockholder who wishes to obtain, without charge, a copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2009, which includes financial statements, and is required to be filed with the SEC, may access it at *www.texasroadhouse.com* in the Investors section or may send a written request to Sheila C. Brown, Corporate Secretary, Texas Roadhouse, Inc., 6040 Dutchmans Lane, Suite 200, Louisville, Kentucky 40205.

OTHER BUSINESS

The Board is not aware of any other matters to be presented at the Annual Meeting other than those set forth herein and routine matters incident to the conduct of the meeting. If any other matters should properly come before the Annual Meeting or any adjournment or postponement thereof, the persons named in the proxy, or their substitutes, intend to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors,

Sheila C. Brown
Corporate Secretary

Louisville, Kentucky
April 9, 2010

Please vote your shares through any of the methods described on the proxy card as promptly as possible, whether or not you plan to attend the Annual Meeting in person. If you do attend the Annual Meeting, you may still vote in person, since the proxy may be revoked at any time before its exercise by delivering a written revocation of the proxy to the Company's Corporate Secretary.

QuickLinks