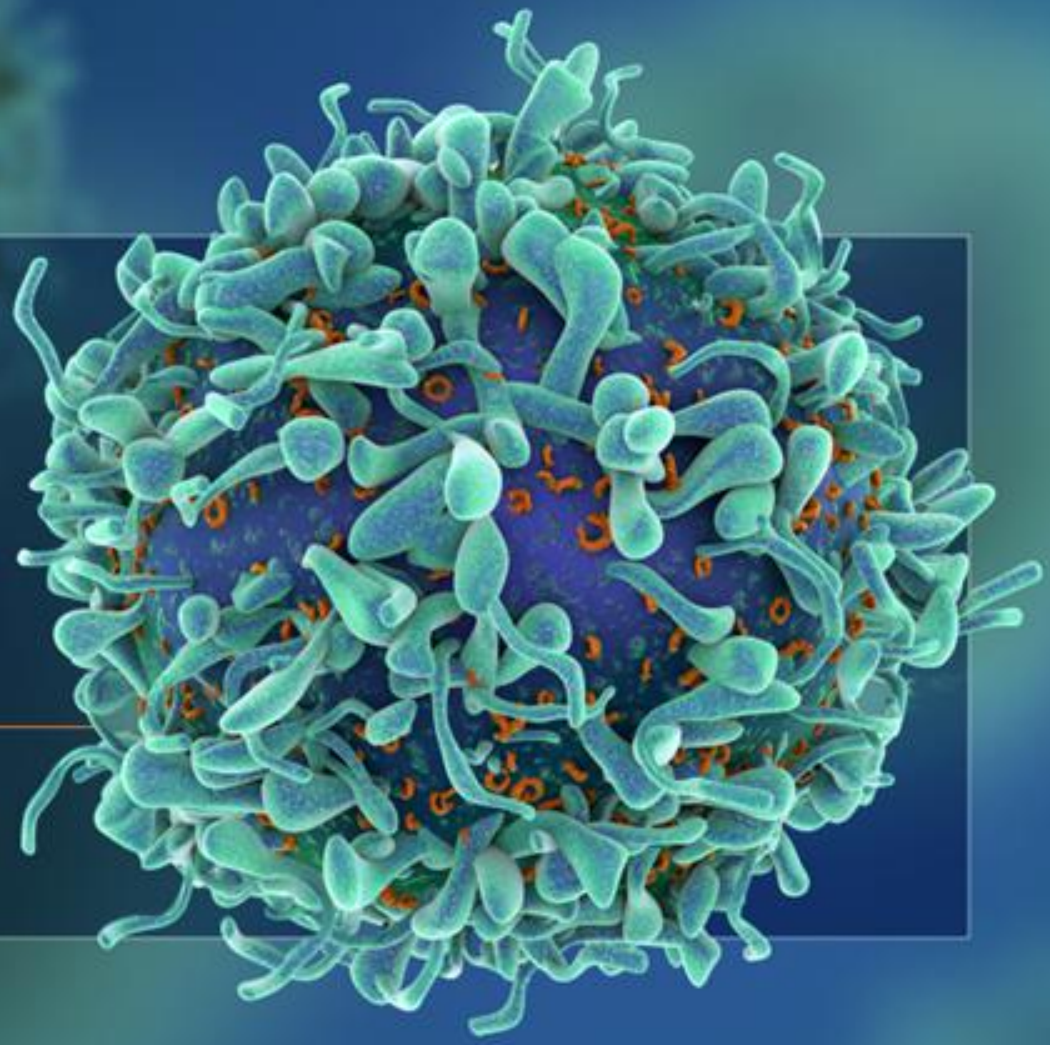
SOLIGENIX

Rising to the Challenges of Rare Disease Treatment

NASDAQ: SNGX



Forward-Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates and their development, regulatory approvals, ability to commercialize our products and product candidates and attract collaborators, reimbursement for our product candidates, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, our ability to obtain and maintain intellectual property protection for our product candidates and their development, competing therapies, and future results of current and anticipated products and product candidates, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, many of which are disclosed in detail in our reports and other documents filed with the Securities and Exchange Commission. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of Soligenix, Inc. internal estimates and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates.

Company Description

Soligenix, Inc. is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need

Two areas of focus:

- A ***Specialized BioTherapeutics segment*** dedicated to the development of products for orphan diseases and areas of unmet medical need in oncology and inflammation

- A ***Public Health Solutions segment*** that develops vaccines and therapeutics for military and civilian applications in the areas of ricin exposure, acute radiation syndrome and emerging and antibiotic resistant infectious disease

Investment Highlights

- **Multiple products with fast track and/or orphan designation, each of which holds potential for significant commercial returns**
- **Three Phase 3 assets, two with data readout approaching**
  - **Cutaneous T-cell lymphoma (SGX301)**
    - Pivotal study in progress; interim analysis ***complete****;* final results ***1Q 2020***
  - **Oral mucositis in head & neck cancer (SGX942)**
    - Pivotal study in progress; interim analysis ***complete****;* final results ***2Q 2020***
  - **Pediatric Crohn's disease (SGX203)**
    - Pivotal study initiation contingent upon additional funding and/or partnership
- **Steady stream of material news to generate attention and build value**
- **Collaborations with biotech, academia and government agencies**
- **Non-dilutive government funding helps cover operating expenses**
  - NIH grant awards of ~$3.0M total for both SGX301 and SGX942 pivotal studies
  - NIH contract award of up to $24.7M supporting the development of RiVax® for pre-exposure to ricin toxin
    - Potential to receive biodefense priority review voucher with US FDA approval
- **Strong management team and renowned advisors with record of success**

Development Pipeline – Rare Diseases

Specialized BioTherapeutics

Product Candidates	Preclinical	Phase 1	Phase 2	Phase 3	Market
SGX301 Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION				*Enrolling*; Ph. 3 data **1Q 2020***
SGX942 Oral Mucositis in Head & Neck Cancer**	FAST TRACK DESIGNATION				*Enrolling*; Ph. 3 data **2Q 2020***
SGX203 Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION				Initiation contingent upon additional funding and/or partnership*
SGX201 Radiation Enteritis**	FAST TRACK DESIGNATION				Initiation contingent upon additional funding and/or partnership*

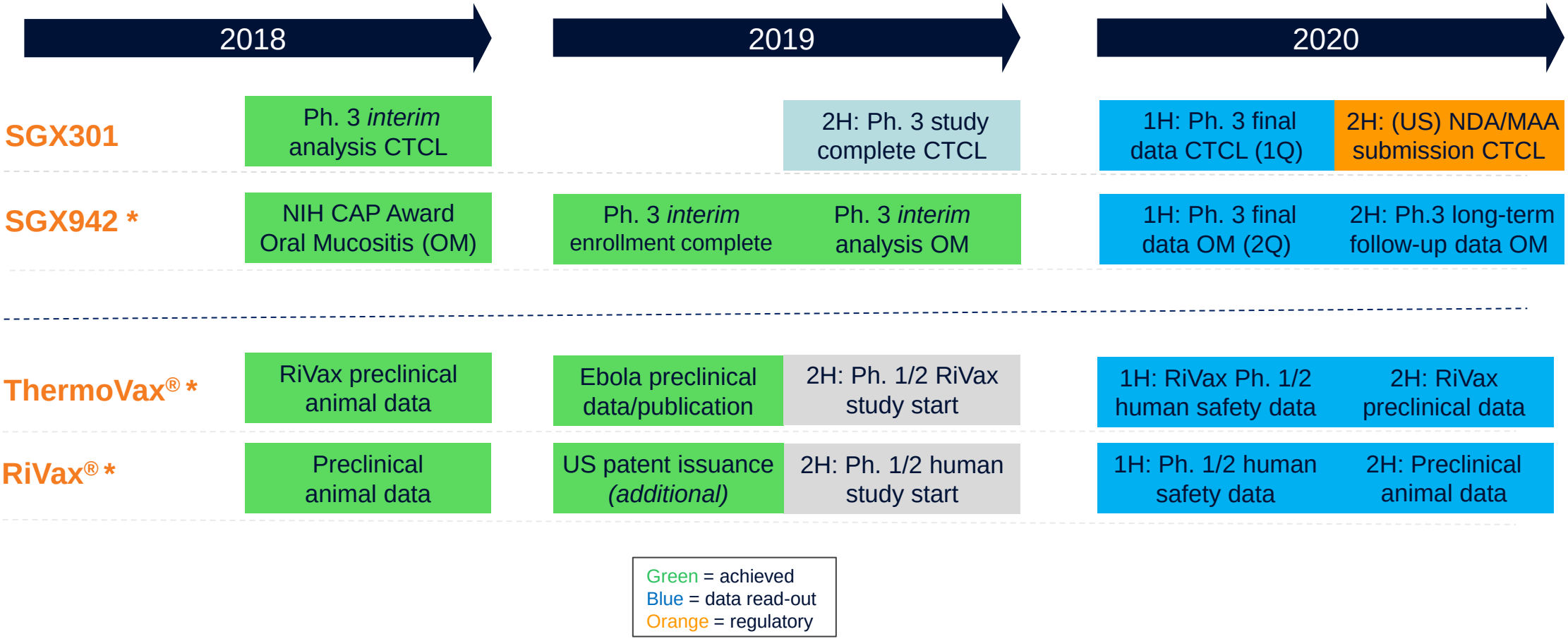
Public Health Solutions**

Product Candidates *(FDA Animal Rule)*	Proof-of-Concept	IND	Phase 1	Phase 2/3	Market
RiVax® + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN DESIGNATION				NIH Contract Award of up to **$24.7M**
OrbeShield® – Therapeutic GI Acute Radiation Syndrome (GI ARS)	ORPHAN & FAST TRACK DESIGNATION				BARDA and NIH Contract Awards of **$18M** collectively
SGX943 – Therapeutic Emerging Infectious Disease	FAST TRACK				USG awards **of $900,000** to date; positive proof of concept preclinical data

Denotes funding in whole or in part by NIH, DTRA, BARDA and/or FDA

* *Anticipated event and timing* **Potential value drivers dependent on continued government funding and/or other funding sources*

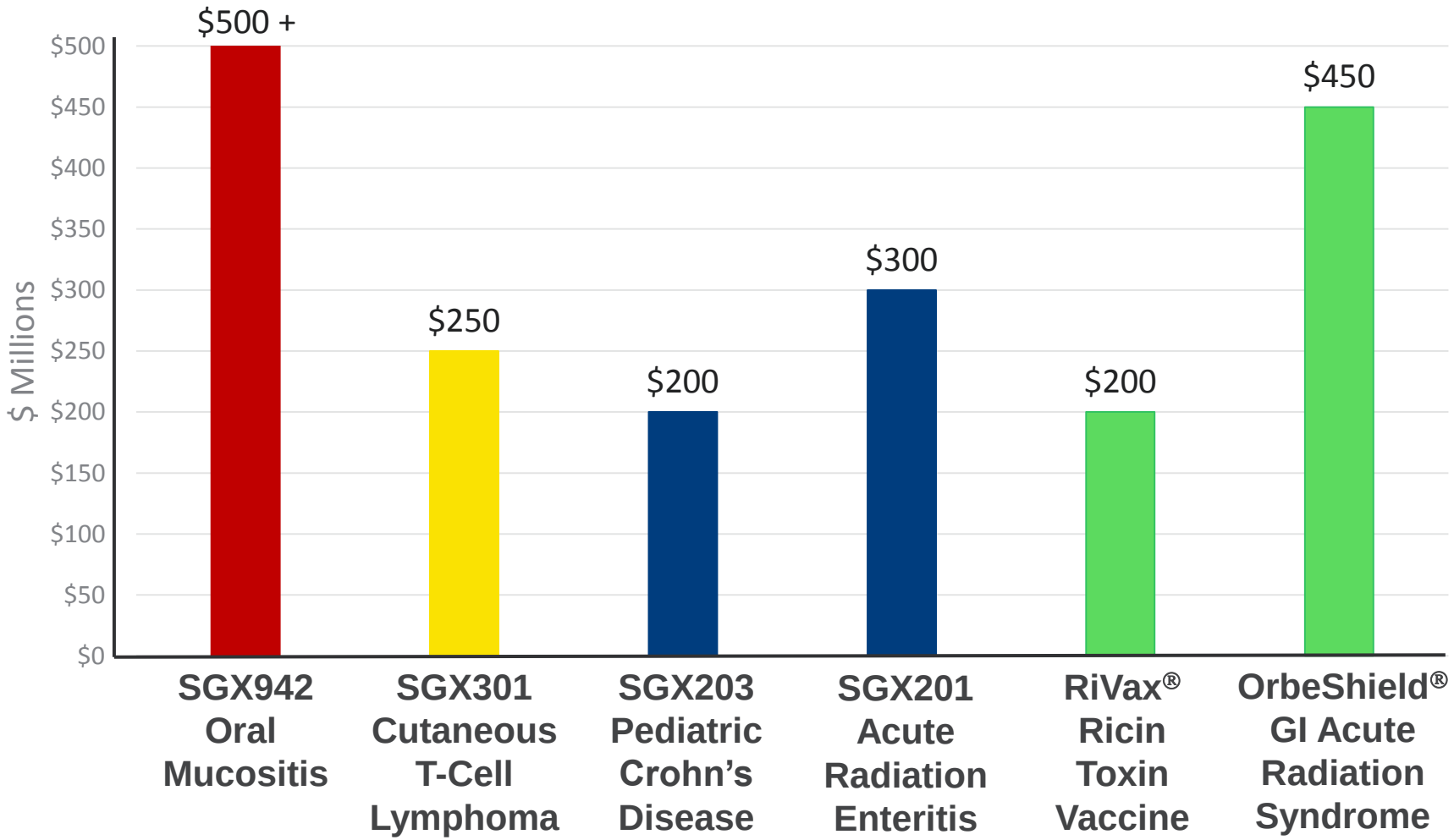
Multiple Potential Value Drivers



Green = achieved
Blue = data read-out
Orange = regulatory

***** *Potential value drivers dependent on continued government funding and/or other funding sources*

Significant Global Market Potential



Assumptions(1)

Oral Mucositis in Head & Neck Cancer
- 90,000 Patients US
- 90,000 Patients EU

Cutaneous T-Cell Lymphoma
- 20,000 Patients US
- 20,000 Patients EU

Pediatric Crohn's Disease
- 80,000 Patients US
- 80,000 Patients EU

Acute Radiation Enteritis in Colorectal Cancer
- 50,000 Patients US
- 50,000 Patients EU

RiVax® Ricin Vaccine
- Assumes 3 year procurement order of $200 million

OrbeShield® GI ARS
- Assumes 3 year procurement order of $450 million

(1) Supporting data on file

Specialized BioTherapeutics

Targeted Approach to Treating Oncology & Inflammation

Specialized BioTherapeutics Segment

Commercial Targets – Unmet Medical Needs in Oncology and Inflammation

Specialized BioTherapeutics

Product Candidates	Preclinical	Phase 1	Phase 2	Phase 3	Market	
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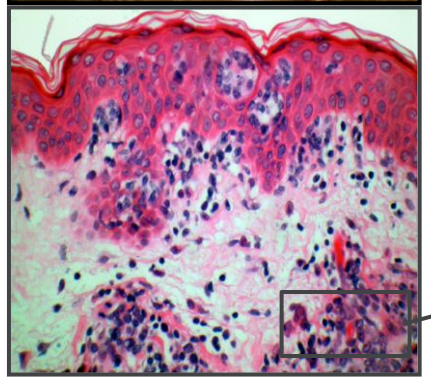
Cutaneous T-Cell Lymphoma – Disease Overview

- **Cutaneous T-cell lymphoma (CTCL)**
  - Rare class of Non-Hodgkin's Lymphoma (NHL)
  - Malignant T-cells migrate to the skin
  - Cancer forms patches, lesions or tumors
- **CTCL affects over 40,000 NHL patients worldwide; currently no cure**
  - $250 million global market potential
- **Two main subtypes of CTCL**
  - Mycosis fungoides (MF) – Early-stage (I-IIA) most common, 88% 5-year survival rate
  - Sézary syndrome (SS) – Advanced-stage, 24% 5-year survival rate
- **No approved first-line therapy for early stage (I-IIA) CTCL (~95% of CTCL patients); *unmet medical need***



SGX301 – Synthetic Hypericin

SGX301 is a first-in-class, topical drug applied to CTCL skin lesions followed by activation with safe, visible, fluorescent light to kill malignant T-cells

Market Opportunity

- No approved front-line therapy for early stage (I-IIA) CTCL (~95% of CTCL patients); unmet medical need
- Most common (unapproved) therapy used for early-stage disease is psoralen given with ultraviolet A (UVA) light, referred to as PUVA
- PUVA contains **Black Box** warning for potential malignancies (melanoma) due to psoralen being mutagenic and light source (UVA) being carcinogenic

Development Status

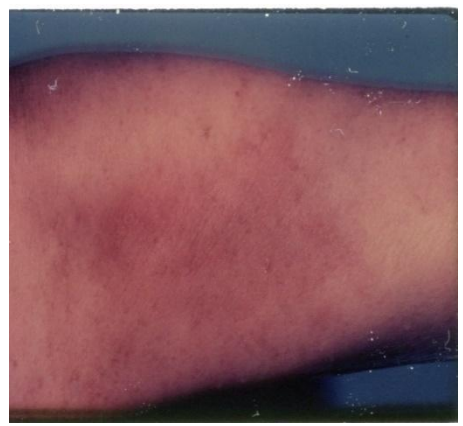
- FDA Orphan Drug and Fast Track designations granted
- UK MHRA Promising Innovative Medicine designation granted
- Phase 1 study demonstrated safety and tolerability
- Phase 2 double-blind, placebo-controlled, multi-center study demonstrated significant ($p \leq 0.04$) response
- Pivotal Phase 3 trial *actively enrolling* ~160 subjects
- NIH grant award of **~$1.5M over 2 years**
- **Interim analysis complete; final results expected 1Q 2020**

SGX301 – Phase 2 Response Rate

CTCL Patch Pre-Therapy

Hypericin Therapy Using Visible Light

CTCL Patch Post -Therapy



Summary of CTCL Lesion Responses to Synthetic Hypericin Ointment Following 6 Weeks of Treatment

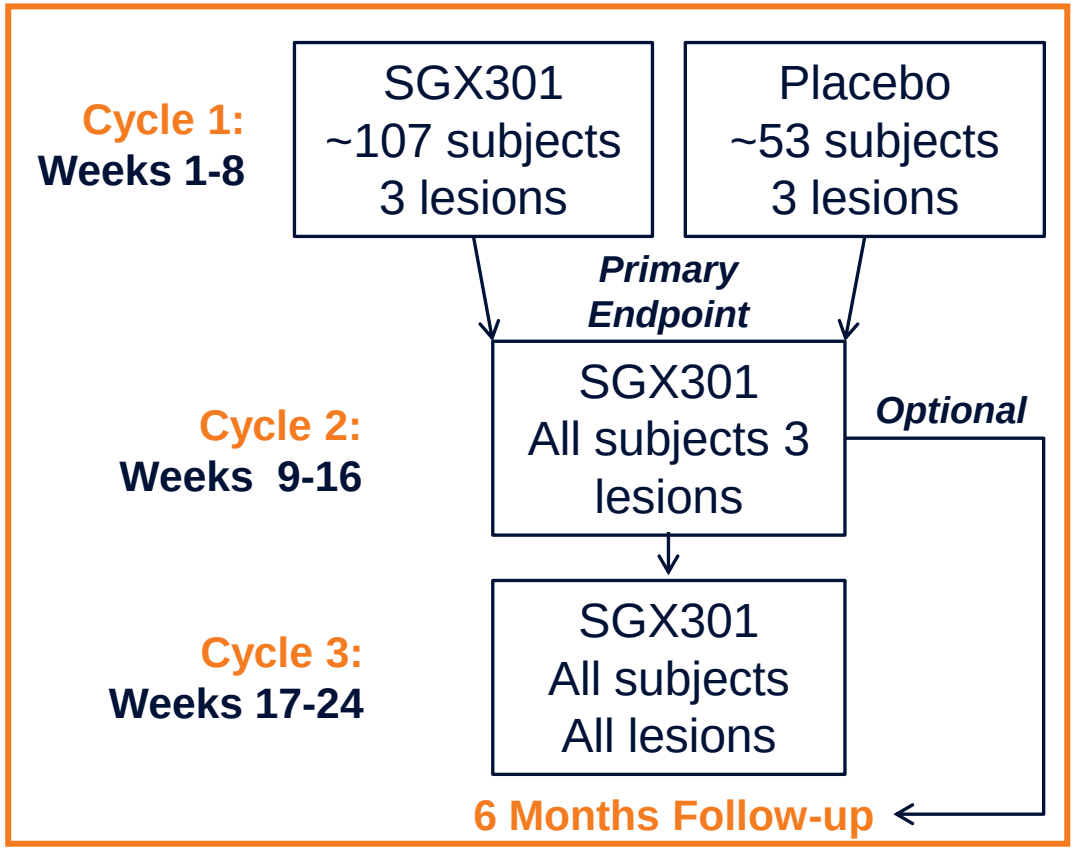
	Responders / Total	Percent Responders
Hypericin Responders	**7/12**	**58.3%**
Placebo Responders	**1/12**	**8.3%**

Note: No serious adverse events other than mild phototoxicity at treated site

Data Source: Journal American Academy Dermatology, Vol 63, Number 6, 2010

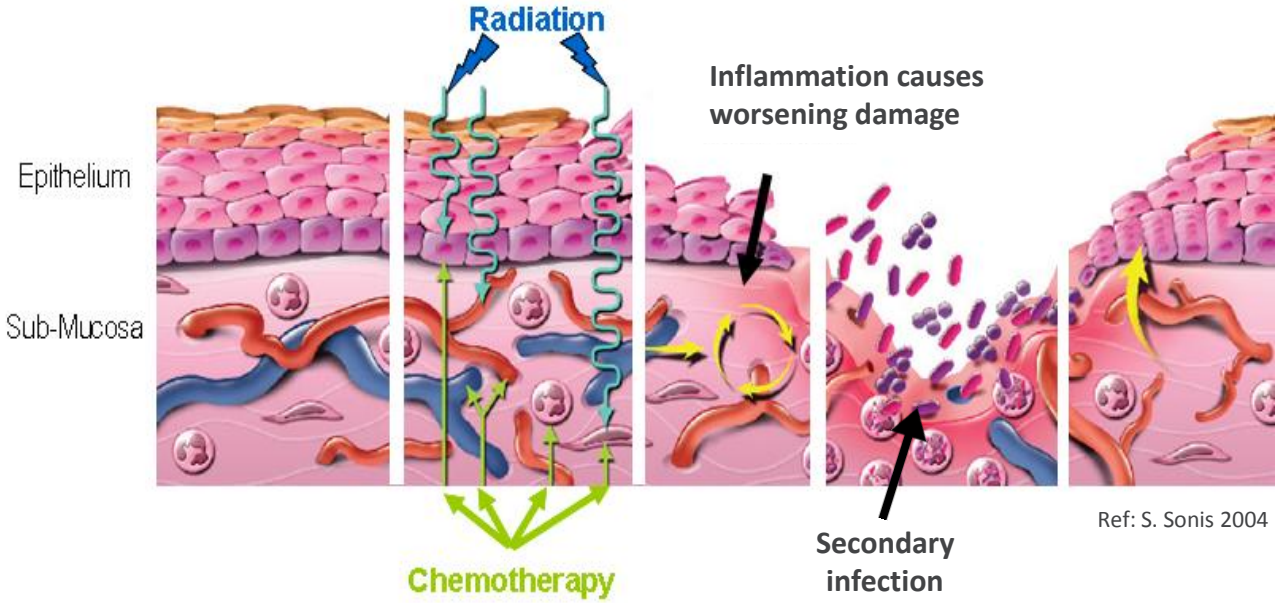
SGX301 – Pivotal Phase 3 Clinical Trial

- **Highly powered, double-blind, placebo-controlled, randomized**
  - Randomized 2:1 (SGX301 [synthetic hypericin] : placebo)
  - Actively enrolling ~160 evaluable subjects across ~35 US study sites
    - Independent interim analysis of ~100 subjects observed beneficial SGX301 effect
    - Sample size adjusted to maintain 90% power calculation
  - ***Final study results 1Q 2020***
- **Primary Endpoint:**
  - Percent of patients achieving a ≥50% cumulative reduction as assessed by the Composite Assessment of Index Lesion Severity (CAILS) scoring system for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline
  - Other key secondary measures: treatment response (including duration), degree of improvement, time to relapse and safety



Oral Mucositis – Disease Overview

- **Oral mucositis (OM)**
  - Multi-factorial disease linked to a dysregulation of the innate immune system
- **OM affects over 180,000 head & neck (H&N) cancer patients worldwide**
  - $500+ million global market potential



- **Debilitating side effect of cancer chemotherapy and/or radiotherapy**
  - Triggering inflammatory cascade
  - Massive ulceration of the mouth, tongue, soft palate and oropharynx
- **Results in**
  - Severe pain causing an inability to eat or drink
  - Reduced tolerance for cancer treatment
  - Significant increases in resource use and cost of care
- **No approved drug for OM in H&N cancer; *unmet medical need***

SGX942 – Innate Defense Regulator

SGX942 (dusquetide) is a first-in-class, injectable drug, called an Innate Defense Regulator (IDR), that modulates the body's innate immune system to reduce inflammation

Market Opportunity

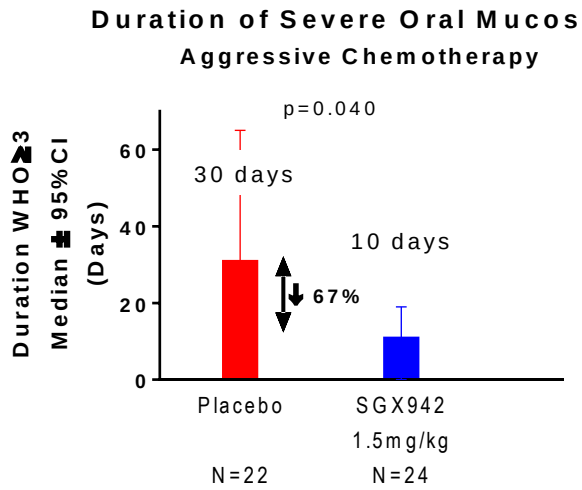
- No approved drug for OM in H&N cancer; unmet medical need
- Only approved drug for OM is palifermin in transplantation; contra-indicated for patients with solid tumors like H&N cancer
- Exclusive commercial collaboration with SciClone in China

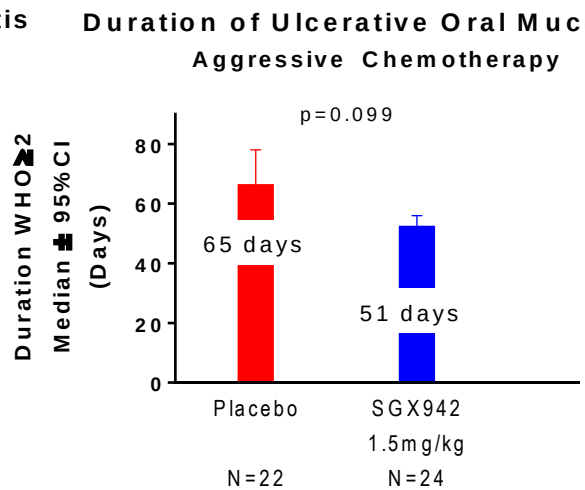
Development Status

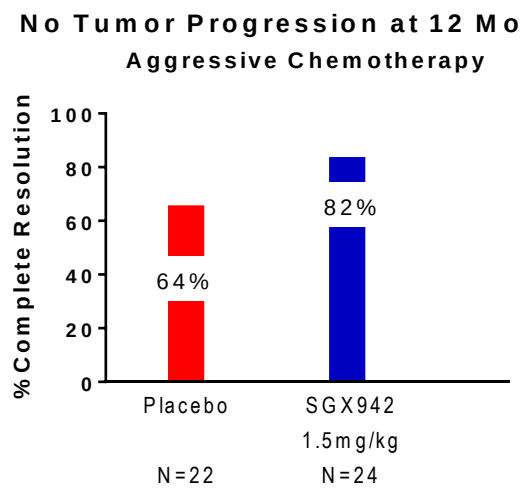
- FDA Fast Track designation granted
- UK MHRA Promising Innovative Medicine designation granted
- Phase 1 study in 84 healthy volunteers demonstrated safety
- Phase 2 double-blind, placebo-controlled, multi-center study in 111 H&N patients demonstrated significant (p=0.04) response
  - **50% reduction** in duration of severe OM in overall population
  - **67% reduction** in duration of severe OM in highest risk population receiving at least 55 Gy radiation and more aggressive (80-100 mg/m^2 every 3rd week) chemotherapy
- Pivotal Phase 3 actively enrolling ~260 subjects
- NIH grant award of **~$1.5M over 2 years**
- **Interim analysis complete; final results expected 2Q 2020**

SGX942 – Phase 2 Study Results

- **Clinically Meaningful Results demonstrated with 1.5 mg/kg dose versus placebo**
  - Reduction in duration of severe OM, coupled with accelerated tumor clearance, reduced infection rate and improved survival
- **Identified patients at highest risk of developing severe OM (80-100 mg/m^2 cisplatin administered every 3rd week)**
  - Increased disease revealed a strong treatment response
    - 67% reduction in severe OM, 27% reduction in ulcerative OM
    - Reduction in incidence of OM
  - Efficacy coupled with an accelerated "complete resolution" of tumor clearance



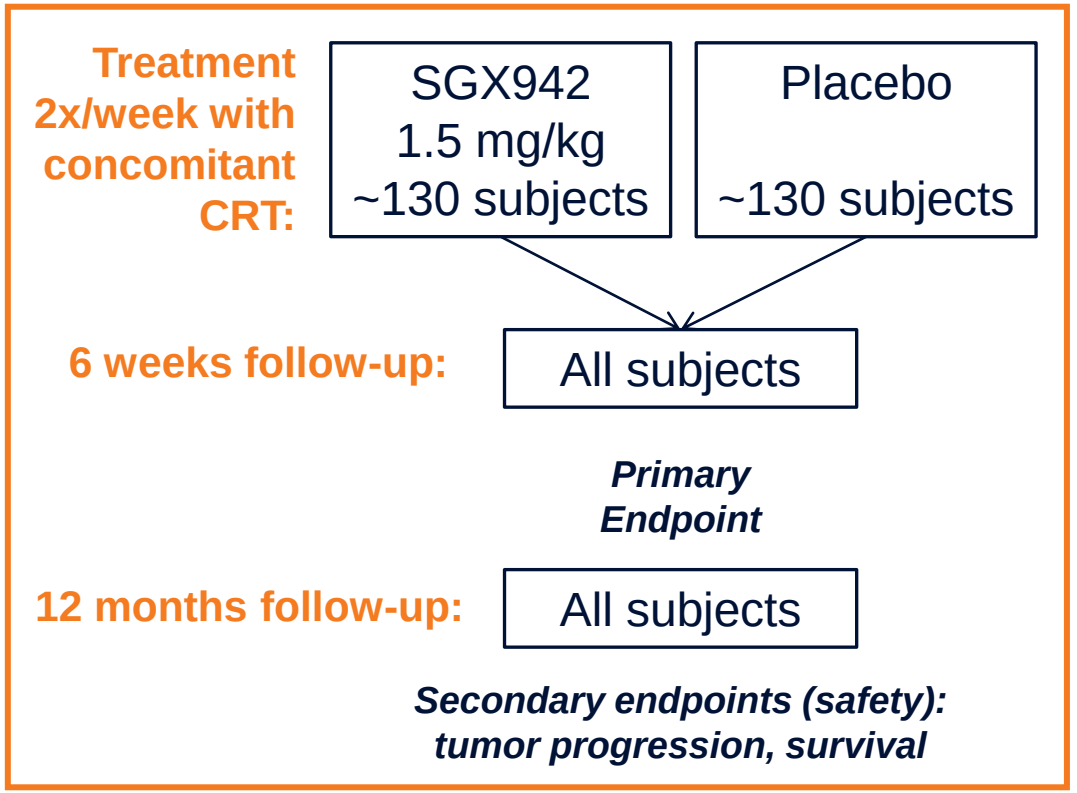




Data Source: *Journal of Biotechnology,* available online 13 October 2016; http://dx.doi.org/10.1016/j.jbiotec.2016.10.010
Biotechnology Reports, available online 17 May 2017; https://doi.org/10.1016/j.btre.2017.05.002

SGX942 – Pivotal Phase 3 Clinical Trial

- **Highly powered, multi-national, double-blind, placebo-controlled, randomized**
  - Head and neck cancer patients receiving chemoradiation therapy including at least 55 Gy fractionated radiation and 80-100 mg/m^2 cisplatin every third week
  - Randomized 1:1 (SGX942 [dusquetide] : placebo)
  - Actively enrolling ~260 subjects across ~50 US/EU study sites
    - Independent interim analysis of ~90 subjects observed beneficial SGX942 effect
    - Sample size adjusted to maintain 90% power calculation
  - ***Final study results 2Q 2020***
- **Primary Endpoint:**
  - Percent decrease in the duration of severe OM
  - Other key secondary measures: incidence of severe OM, infection, tumor resolution, survival, safety



Public Health Solutions

Addressing Critical Concerns for Industry and Government

Public Health Solutions Segment

Funded by Government – Medical Countermeasures (MCMs) for Civilian and Military Use

Public Health Solutions**

Product Candidates *(FDA Animal Rule)*	Proof-of-Concept	IND	Phase 1	Phase 2/3	Market
RiVax® + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN DESIGNATION				NIH Contract Award of up to **$24.7M**
OrbeShield® – Therapeutic GI Acute Radiation Syndrome (GI ARS)	ORPHAN & FAST TRACK DESIGNATION				BARDA and NIH Contract Awards of **$18M** collectively
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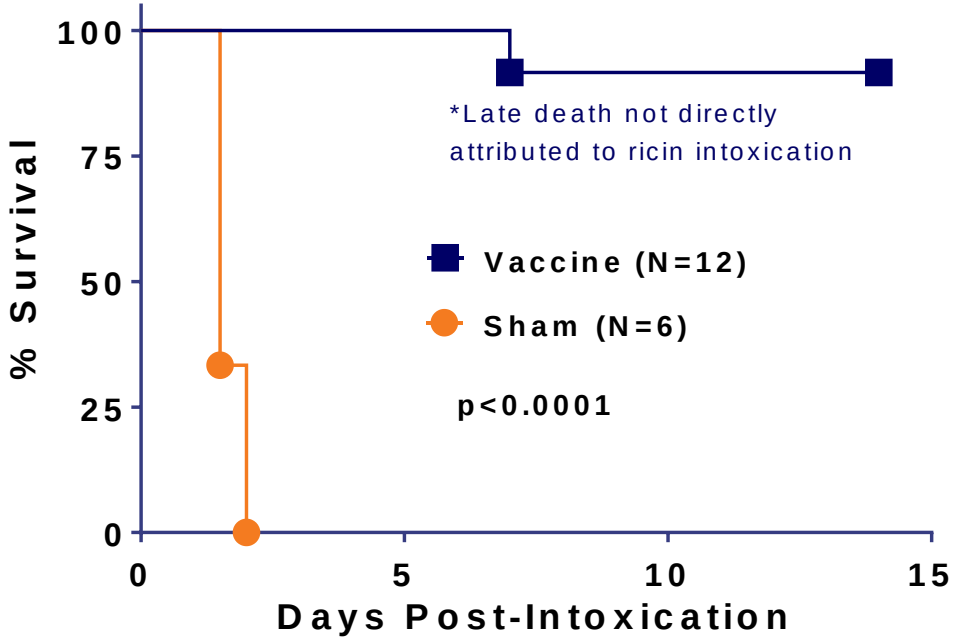
With FDA MCM approval, potential to be awarded:

- **Biodefense Priority Review Voucher**
  to be used for future programs or sold, and/or
- **Government Procurement Contract**
  for supplying strategic national stockpile

RiVax® – Ricin Toxin Vaccine

Heat-stable ricin vaccine provided 100% protection in a non-human primate aerosol challenge model (right)

Demonstrated safety in Phase 1 studies



Market Opportunity

- Ricin toxin vaccine of rising interest to US due to recent terrorist threats and ease of castor bean procurement and ricin production
- Government has placed priority on development activities
- Potential to be first approved ricin toxin vaccine
- Potential for RiVax® to qualify for Priority Review Voucher

Development Status

- FDA and EU Orphan Drug designations granted
- Development collaboration with Emergent BioSolutions & IDT Biologika for manufacturing
- NIH contract award of up to **$24.7M over 6 years**, including Phase 1/2 clinical study

Experienced Management and Board of Directors

Christopher J. Schaber, PhD President & CEO	• 30 years of experience • Discovery Laboratories (COO) • Acute Therapeutics (Co-Founder) • Ohmeda Pharmaceuticals • The Liposome Company • Wyeth Ayerst
Richard Straube, MD Chief Medical Officer	• 30 years of experience • Stealth Peptides Inc. • INO Therapeutics • Ohmeda Pharmaceuticals • Centocor
Oreola Donini, PhD Chief Scientific Officer	• 15 years of experience • Inimex Pharmaceuticals • ESSA Pharma, Inc. • Kinetek Pharmaceuticals
Jonathan Guarino, CPA, CGMA Chief Financial Officer	• 22 years of experience • Hepion Pharmaceuticals, Inc. • Covance, Inc. • BlackRock, Inc. • Barnes & Noble, Inc. • PricewaterhouseCoopers LLP

Gregg Lapointe, CPA, MBA	• 20 years of experience • Cerium Pharmaceuticals (CEO) • Formerly of Sigma-Tau Pharmaceuticals, AstenJohnson, PricewaterhouseCoopers
Diane Parks	• 30 years of experience • Formerly of Kite Pharma, Pharmacyclics, Amgen, Genentech
Mark Pearson	• 25 years of experience • Altamont Pharmaceutical Holdings, LLC • Annex Ventures (Co-Founder) • Drawbridge Reality (Co-Founder) • CRESA Partners LLC (Co-Founder)
Robert Rubin, MD	• 36 years of experience • The Lewin Group • Georgetown School of Medicine • Former Assistant Surgeon General of the United States
Jerome Zeldis, MD, PhD	• 33 years of experience • Sorrento Therapeutics (CMO) • Formerly of Celgene Corporation (CMO), Sandoz, Janssen Research Institute

In Summary

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www.soligenix.com

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