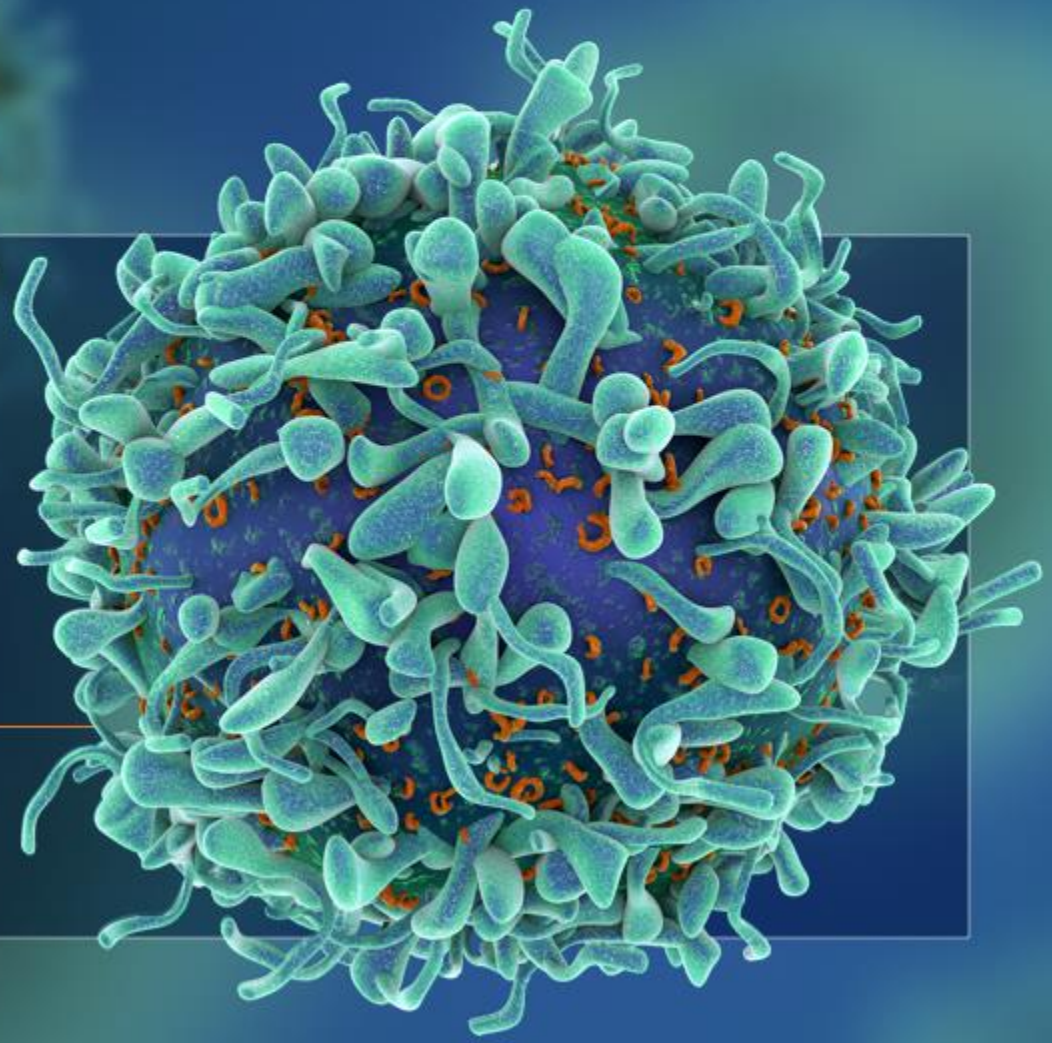
SOLIGENIX

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 and uncertainties, such as experienced with the COVID-19 outbreak, 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, emerging and antibiotic resistant infectious disease, and viral disease including Ebola, Marburg and COVID-19

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)**
    - ***Positive statistically significant final results achieved***; follow-up ongoing
  - **Oral mucositis in head & neck cancer (SGX942)**
    - Pivotal study in progress; interim analysis ***complete;*** final results ***4Q 2020*** *(adjusted for COVID-19 disruption)*
  - **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 ~$21.2 M 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				**Positive primary + Cycle 2 results**
SGX942 Oral Mucositis in Head & Neck Cancer	FAST TRACK DESIGNATION				*Over-enrolling* [COVID-19]; Ph. 3 data **4Q 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 & FAST TRACK DESIGNATION				NIH Contract Award of **$21.2M**
SGX943 – Therapeutic Emerging Infectious Disease	FAST TRACK				USG awards of **$900,000** to date; positive proof of concept preclinical data
ThermoVax® – Vaccine Heat Stabilization Technology					Ebola/Marburg: **$700,000** Grant Subaward; COVID-19: Collaboration with University of Hawai'i at Mānoa

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*

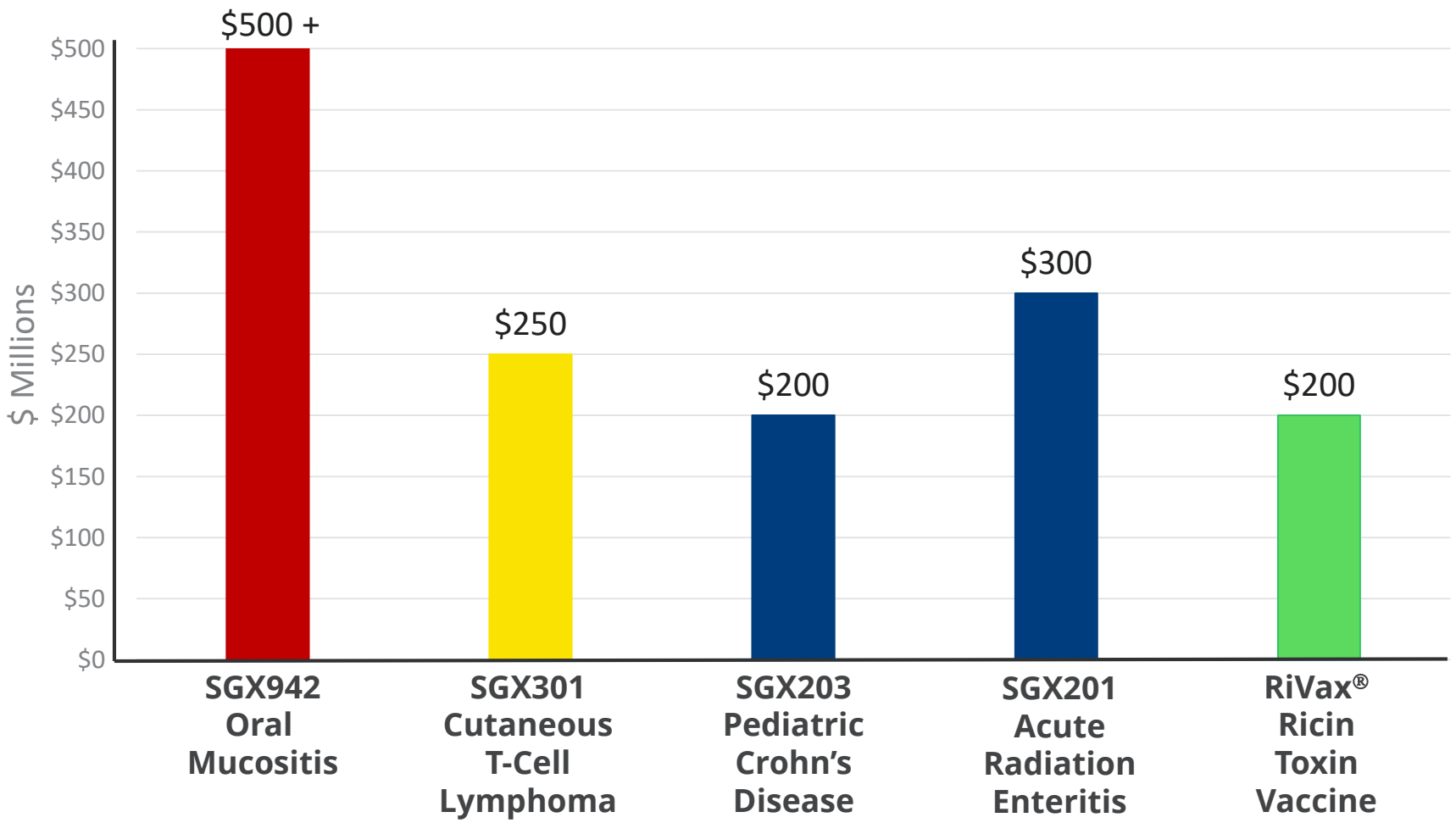
Multiple Potential Value Drivers

	2018	2019		2020**	
SGX301-CTCL	Ph. 3 *interim* analysis CTCL		Ph. 3 study complete CTCL	Ph. 3 primary endpoint + Cycle 2	2H: Ph. 3 final Cycle 3 + follow-up
SGX942-OM	NIH CAP Award Oral Mucositis (OM)	Ph. 3 *interim* enrollment complete	Ph. 3 *interim* analysis OM	Ph. 3 260 pt. target enrollment reached	2H: Ph. 3 final topline data OM
RiVax® *	Preclinical animal data	US patent issuance *(additional)*	Ph. 1/2 human study start	FDA Fast Track designation	2H: Preclinical animal data
SGX943 *	Preclinical animal data		DTRA Subaward		2H: Preclinical animal data
ThermoVax® *	RiVax preclinical animal data	Ebola preclinical data/publication	Ph. 1/2 RiVax study start	1H: MARV preclinical data	2H: Coronavirus preclinical data

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

* *Potential value drivers dependent on continued government funding and/or other funding sources*
** *Timelines subject to potential disruption due to COVID-19 outbreak*

Significant Global Market Potential



Assumptions(1)

Oral Mucositis in Head & Neck Cancer

- 90,000 Patients US
- 90,000 Patients EU

Cutaneous T-Cell Lymphoma

- 27,000 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

(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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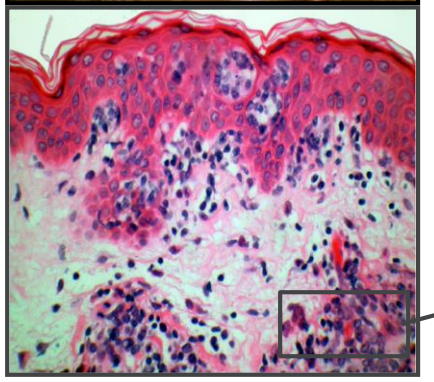
Cutaneous T-Cell Lymphoma – Disease Overview

- **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 secondary treatments carry significant risks for melanoma (potentially lethal side effect of treatment) and additional skin damage

Development Status

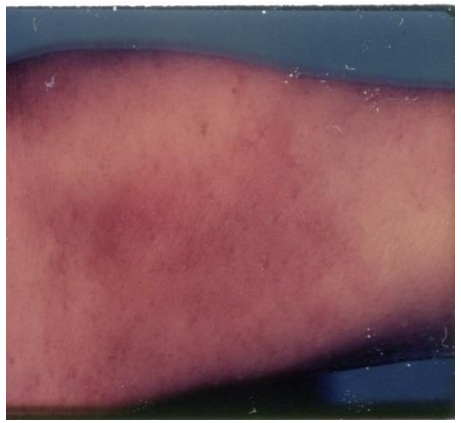
- FDA Orphan Drug and Fast Track designations granted
- UK MHRA Promising Innovative Medicine designation granted
- Phase 1 study demonstrated safety and tolerability
- Phase 2 study demonstrated significant ($p \leq 0.04$) response
- Pivotal Phase 3 trial enrolled 169 subjects
  - **Primary endpoint statistically significant ($p \leq 0.04$):** Minimal 6-week treatment (Cycle 1) resulted in a 50% reduction of cumulative lesion score in 16% of treated patients
  - **Statistically significant increase in positive response rate ($p < 0.0001$)** with extended treatment (12 weeks vs. 6 weeks treatment) yielding a **40% response**
  - Optional Cycle 3 and long-term follow-up ongoing
- NIH grant award of **~$1.5M over 2 years**
- **Topline final results statistically significant; Phase 3 follow-up ongoing**

SGX301 – Ointment + Light

CTCL Patch Pre-Therapy

Hypericin Therapy Using Visible Light

CTCL Patch Post -Therapy

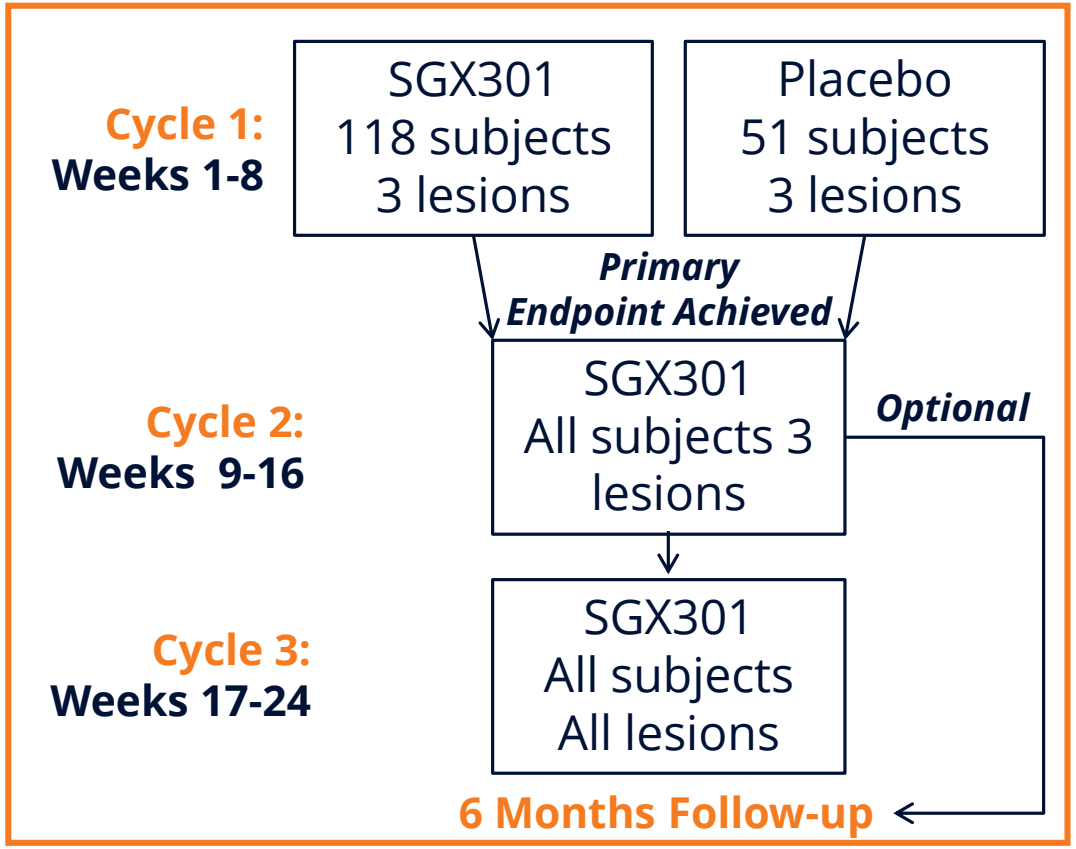


- **Treatment safe and well-tolerated:**
  - Treatment well-tolerated with minimal reported adverse events
  - Uses visible fluorescent light (***not*** carcinogenic unlike other phototherapy or photodynamic therapy used in CTCL)
- **Rapid treatment response:**
  - Most CTCL treatments require at least 12 months to observe a statistically significant response
  - Phase 3 data demonstrates statistical significance at 6 weeks with improved responses (40%) through 12 weeks

SGX301 – Pivotal Phase 3 Clinical Trial

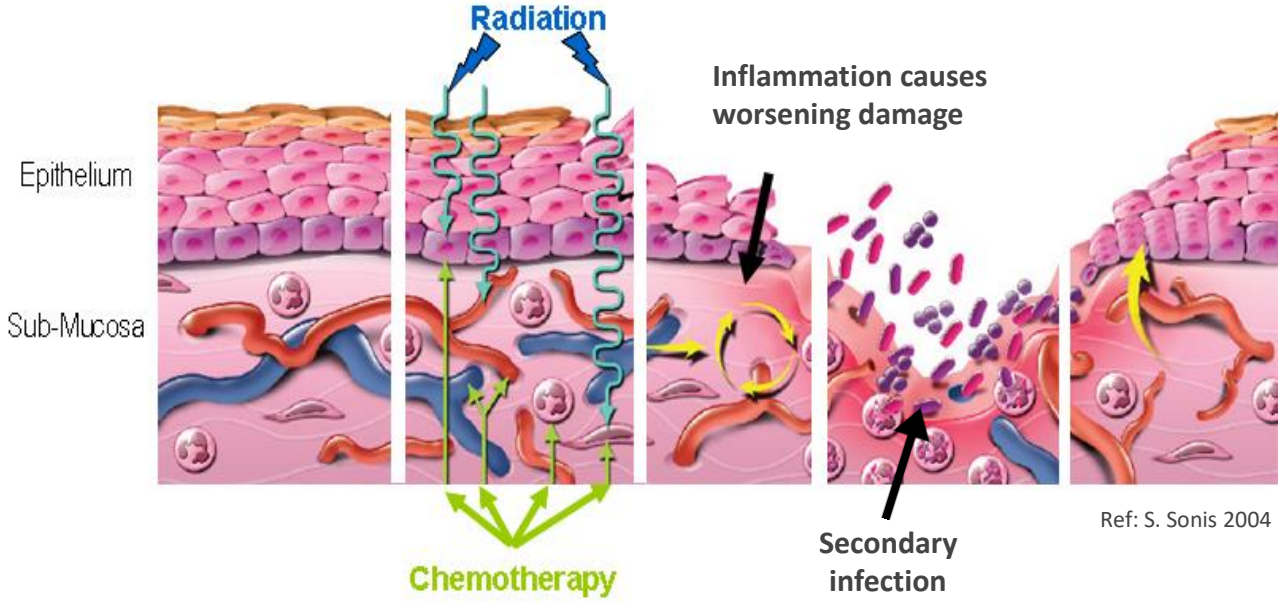
- **Highly powered, double-blind, placebo-controlled, randomized**
  - Randomized 2:1 (SGX301 [synthetic hypericin 0.25%] : placebo)
  - 169 subjects enrolled across US
  - **Cycle 1 complete: Primary Endpoint statistically significant (p=0.04)**
  - **Cycle 2 complete: Statistically significant improvement in treatment response of 40% (p<0.0001)**
  - **Cycle 3 and long-term follow-up ongoing**

- **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

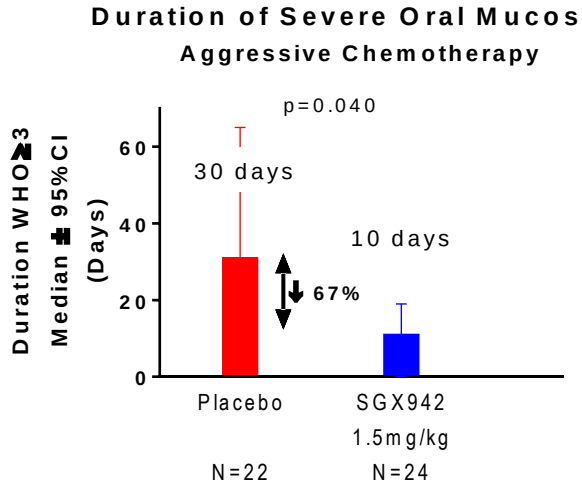
- No approved drug for OM in H&N cancer; unmet medical need
- Only approved drug for OM is palifermin in transplantation; contra-indicated for patients with solid tumors like H&N cancer
- Exclusive commercial collaboration with SciClone in China

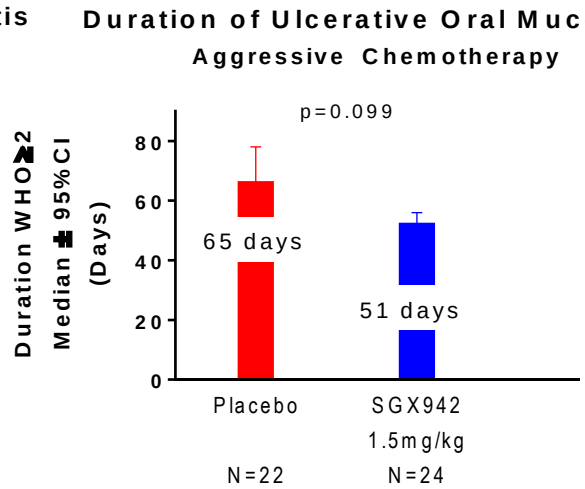
Development Status

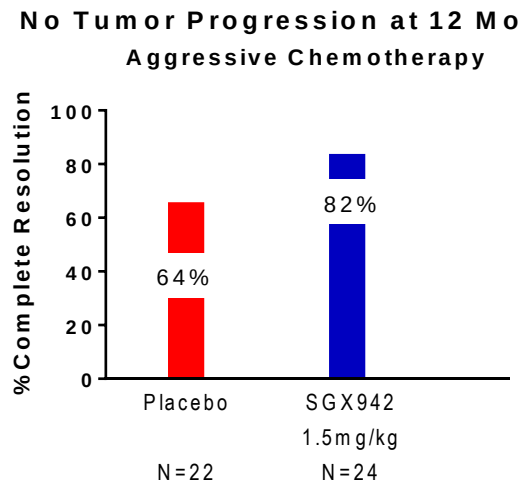
- FDA Fast Track designation granted
- UK MHRA Promising Innovative Medicine designation granted
- Phase 1 study in 84 healthy volunteers demonstrated safety
- Phase 2 double-blind, placebo-controlled, multi-center study in 111 H&N patients demonstrated significant (p=0.04) response
  - **50% reduction** 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 *over-enrolling to* ~285 subjects (~25 added due to COVID-19)
- NIH grant award of **~$1.5M over 2 years**
- **Interim analysis complete; topline final results expected 4Q 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



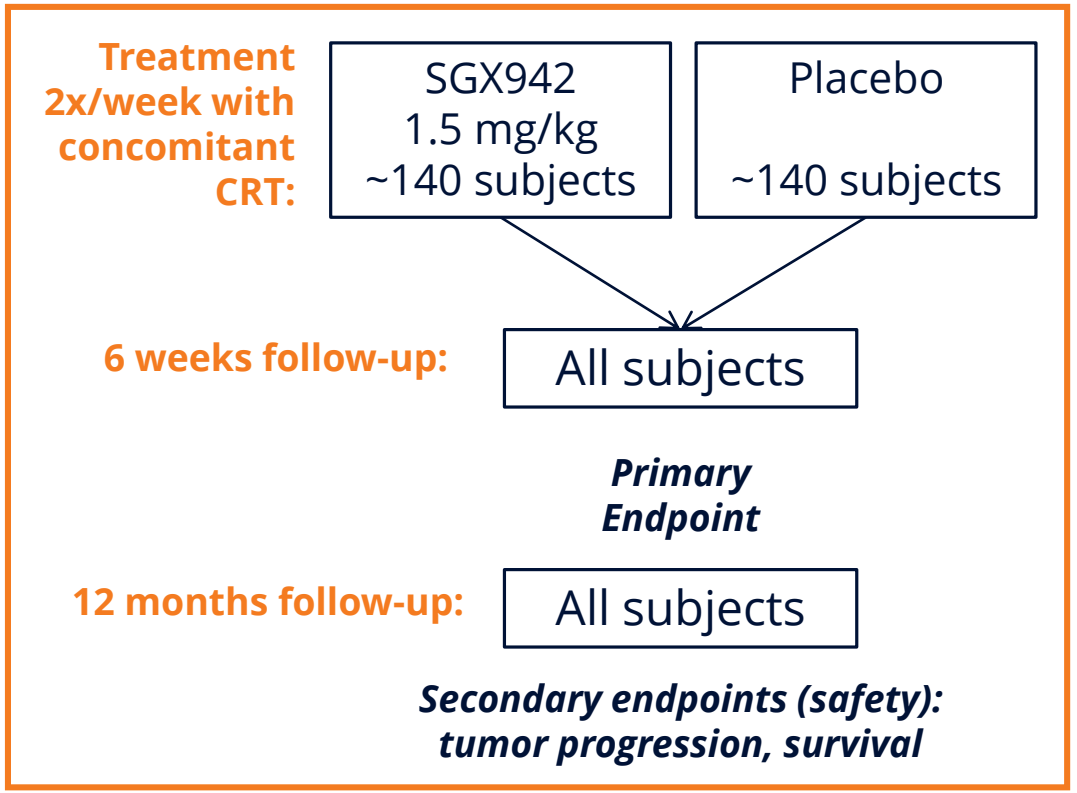




Data Source: *Journal of Biotechnology,* available online 13 October 2016; http://dx.doi.org/10.1016/j.jbiotec.2016.10.010
Biotechnology Reports, available online 17 May 2017; https://doi.org/10.1016/j.btre.2017.05.002

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 ~285 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
  - ***Topline final results 4Q 2020***
- **Primary Endpoint:**
  - Percent decrease in the duration of severe OM
  - Other key secondary measures: incidence of severe OM, infection, tumor resolution, survival, safety



* Increase of ~25 subjects to account for potential impact of COVID-19

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
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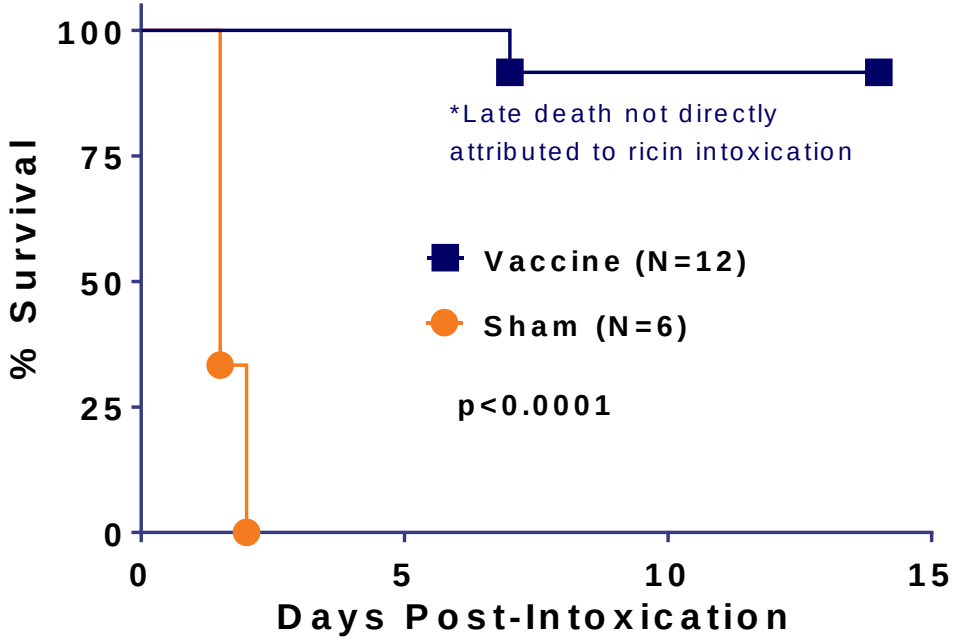
With FDA MCM approval, potential to be awarded:

- **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

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 Orphan Drug and Fast Track designations granted
- Development collaboration with Emergent BioSolutions & IDT Biologika for manufacturing
- NIH contract award of **~$21.2M over 6 years**

Experienced Management and Board of Directors

Christopher J. Schaber, PhD Chairman, 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	• 20 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	• 25 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
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

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Thank you

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www.soligenix.com

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