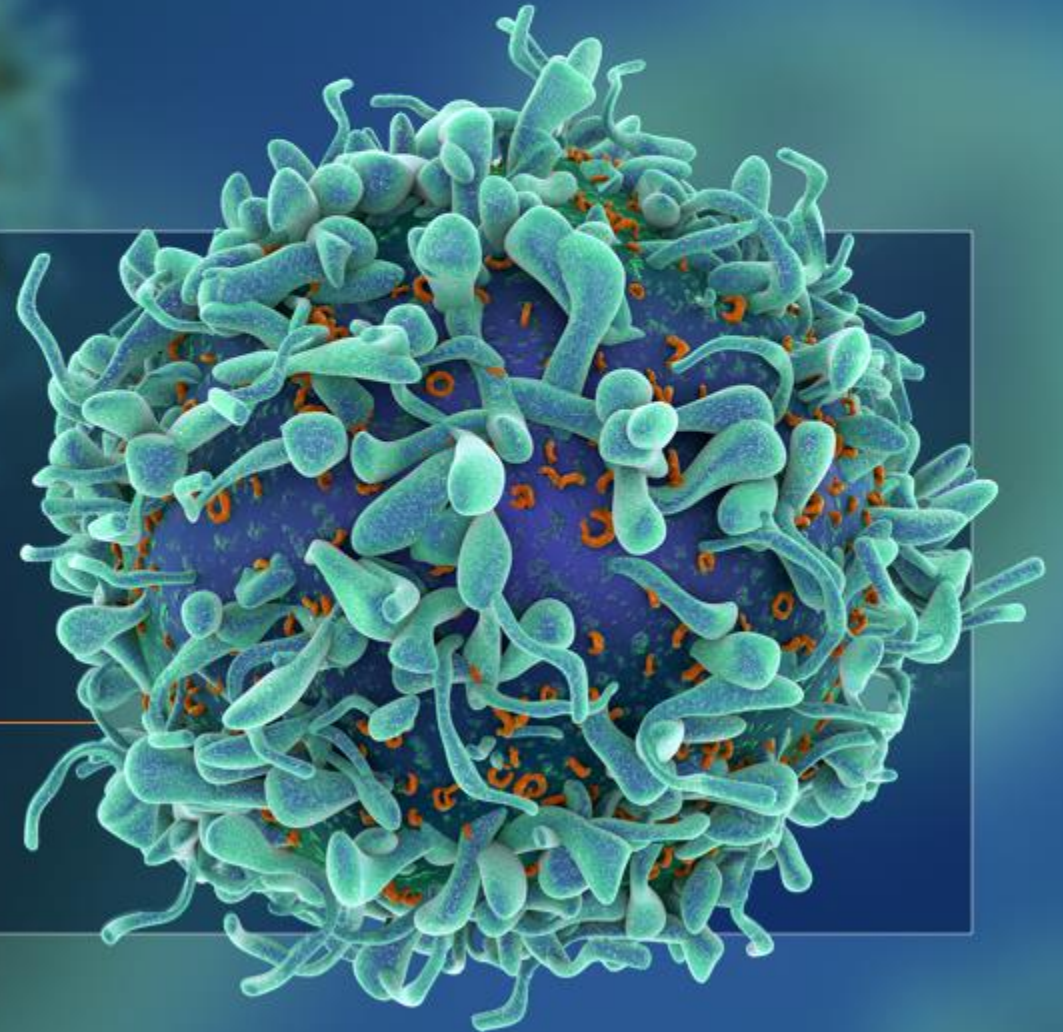




# Rising to the Challenges of Rare Disease Treatment

**NASDAQ: SNGX**

January 08, 2024



# 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

- Robust pipeline consisting of multiple fast track and/or orphan designated products, with potential for significant commercial returns of ~\$2B in global annual sales
- Late clinical-stage assets, one with successful Phase 3 data readout
  - **Cutaneous T-cell lymphoma (HyBryte™ or SGX301)**
    - **Positive statistically significant results achieved in first Phase 3 study**; published JAMA Dermatology
    - Actively engaged in FDA and EMA discussions regarding feasible trial design for second confirmatory Phase 3 study
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$250M**
  - **Psoriasis (SGX302)**
    - **Positive and statistically significant results achieved in Phase 1/2 proof of concept (POC) study**
    - Phase 2a study in mild-to-moderate psoriasis **ongoing; clinical success achieved in 2 of 4 Cohort 2 patients**
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$1B**
  - **Behçet's disease (SGX945)**
    - Phase 2a study in aphthous ulcers in Behçet's Disease; **FDA IND, protocol clearance and fast track received**
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$200M**
- Collaborations with biotech, academia and government agencies
- Non-dilutive government funding helps cover operating expenses
  - NIH grant awards supporting vaccine development; potential for up to 3 Priority Review Vouchers (PRVs)
- Experienced management team and renowned advisors with record of success

**HyBryte**

(hypericin sodium) ointment 0.25%

# Development Pipeline – Rare Diseases

## Specialized BioTherapeutics

Product Candidates*	Preclinical	Phase 1	Phase 2	Phase 3	NDA Review	Market
<b>HyBryte™</b> ( <i>synthetic hypericin sodium</i> ) Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION			Positive Phase 3 study results; Engaged in FDA/EMA discussions regarding design of 2 <sup>nd</sup> Phase 3 study		
<b>SGX942</b> ( <i>dusquetide</i> ) Oral Mucositis in Head & Neck Cancer**	FAST TRACK DESIGNATION			2 <sup>nd</sup> Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX203</b> ( <i>beclomethasone dipropionate</i> ) Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION			Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX302</b> ( <i>synthetic hypericin sodium</i> ) Mild-to-Moderate Psoriasis				Positive proof-of-concept demonstrated in Phase 1/2 pilot study; Phase 2a study ongoing		
<b>SGX945</b> ( <i>dusquetide</i> ) Apthous Ulcers in Behçet's Disease	FAST TRACK DESIGNATION			FDA IND and Phase 2a protocol clearance received		

## Public Health Solutions\*\*

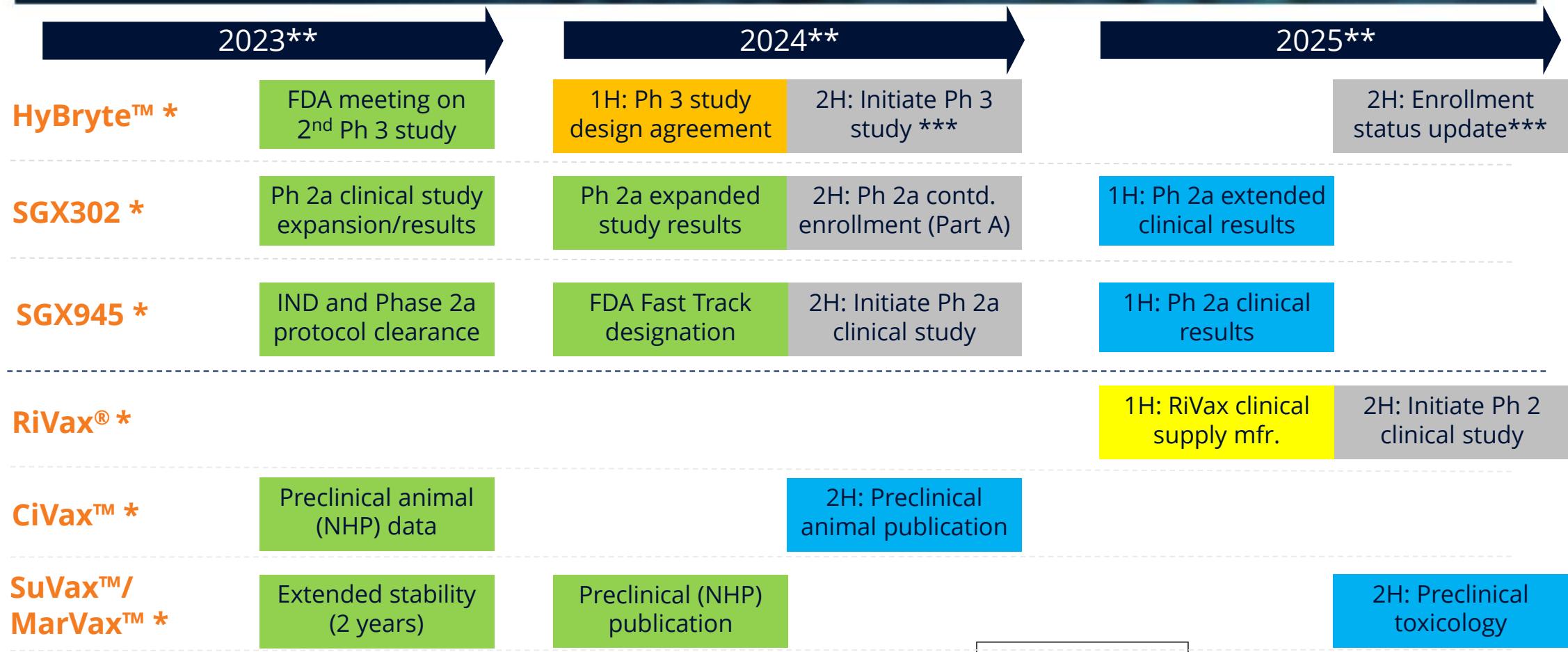
Product Candidates (FDA Animal Rule)*	Proof-of-Concept	IND	Phase 1	Phase 2/3	BLA Review	Market
<b>RiVax®</b> + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN & FAST TRACK DESIGNATION			NIH Contract Awards of <b>\$30M</b> to date; positive preclinical and clinical data		
<b>SuVax™ / MarVax™</b> + ThermoVax® – Filovirus Vaccines				NIH Grant Subaward of <b>\$700,000</b> to date; positive preclinical data		
<b>CiVax™</b> + ThermoVax® – Vaccine COVID-19				NIH Grant Award of <b>\$1.5M</b> to date; positive preclinical data		

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

\* Anticipated event and timing subject to COVID-19 disruption

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

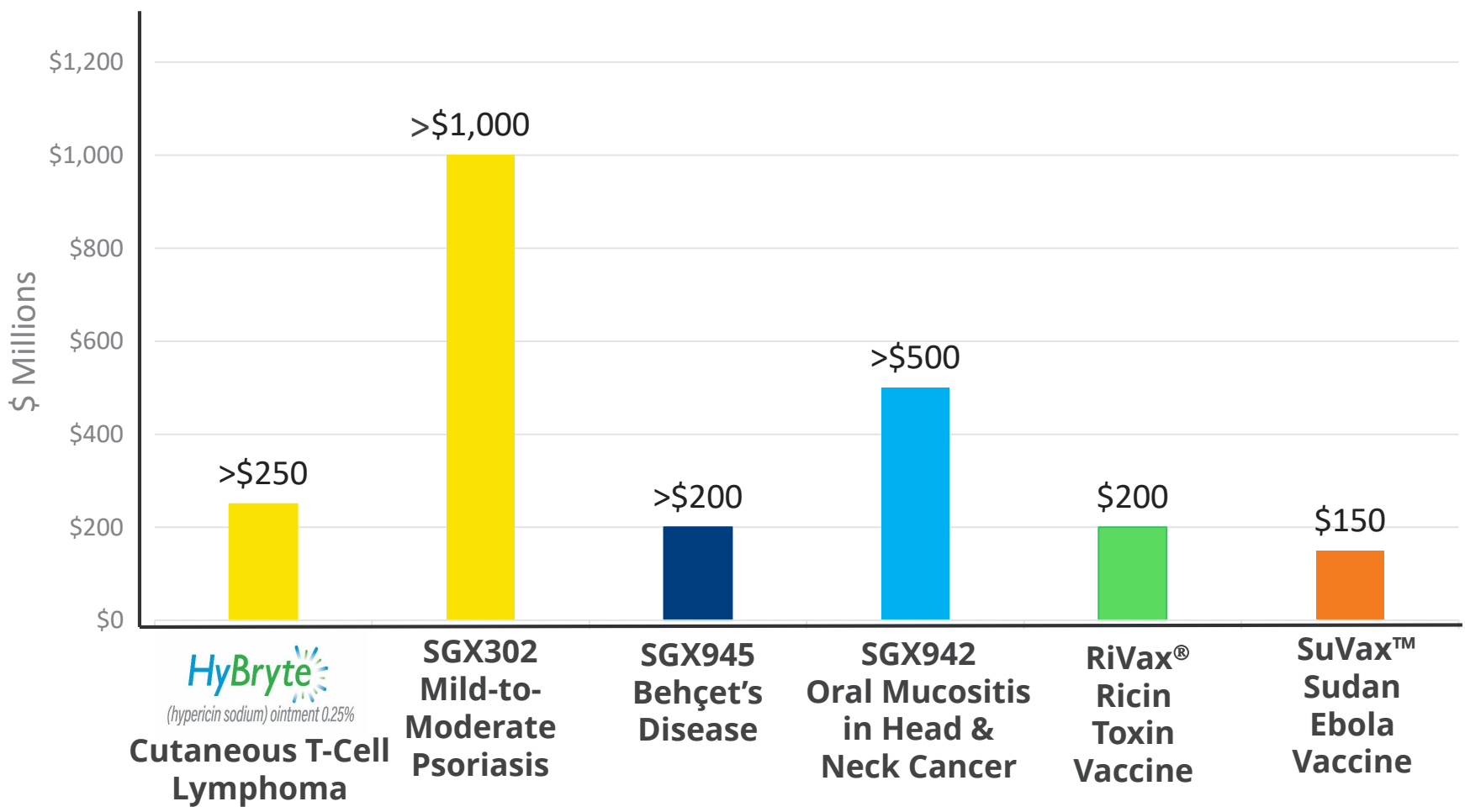
# Multiple Potential Value Drivers



\* Potential value drivers dependent on continued government funding and/or other funding sources  
 \*\* Timelines subject to potential disruption due to COVID-19 outbreak  
 \*\*\* Assumes agreement on feasible second Phase 3 trial design

Green = achieved  
 Blue = data read-out  
 Grey = clinical  
 Orange = regulatory  
 Yellow = nonclinical

# Total Addressable Global Market



Assumptions <sup>(1)</sup>	
<b>Cutaneous T-Cell Lymphoma</b>	27,000 Patients US 20,000 Patients EU
<b>Mild-to-Moderate Psoriasis</b>	3,000,000 Patients US 5,000,000 Patients EU
<b>Behçet's Disease</b>	18,000 Patients US 80,000 Patients EU
<b>Oral Mucositis in Head &amp; Neck Cancer</b>	90,000 Patients US 90,000 Patients EU
<b>RiVax® Ricin Vaccine</b>	Assumes 5 year procurement order of \$200 million ( <i>PRV potential</i> )
<b>SuVax™ Ebola Vaccine</b>	Assumes 5 year procurement order of \$150 million ( <i>PRV potential</i> )

(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

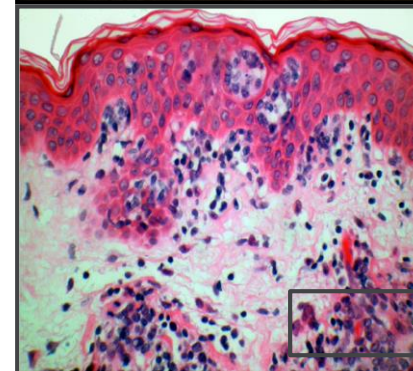
Product Candidates*	Preclinical	Phase 1	Phase 2	Phase 3	NDA Review	Market
<b>HyBryte™ (synthetic hypericin sodium)</b> Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION			<b>Positive Phase 3 study results;</b> Engaged in FDA/EMA discussions regarding design of 2 <sup>nd</sup> Phase 3 study		
<b>SGX942 (dusquetide)</b> Oral Mucositis in Head & Neck Cancer**	FAST TRACK DESIGNATION			2 <sup>nd</sup> Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX203 (beclomethasone dipropionate)</b> Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION			Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX302 (synthetic hypericin sodium)</b> Mild-to-Moderate Psoriasis				Positive proof-of-concept demonstrated in Phase 1/2 pilot study; Phase 2a study ongoing		
<b>SGX945 (dusquetide)</b> Apthous Ulcers in Behçet's Disease	FAST TRACK DESIGNATION			FDA IND and Phase 2a protocol clearance received		

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

\* Anticipated event and timing subject to COVID-19 disruption \*\*Potential value drivers dependent on continued government funding and/or other funding sources

# 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 total addressable global market; >\$90 million in US
- **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 (~90% of CTCL patients); *unmet medical need***



Atypical T-cells  
in dermis

# HyBryte™ – Synthetic Hypericin Sodium Ointment + Light Activation, First-in-Class



## ➤ Treatment safe and well-tolerated

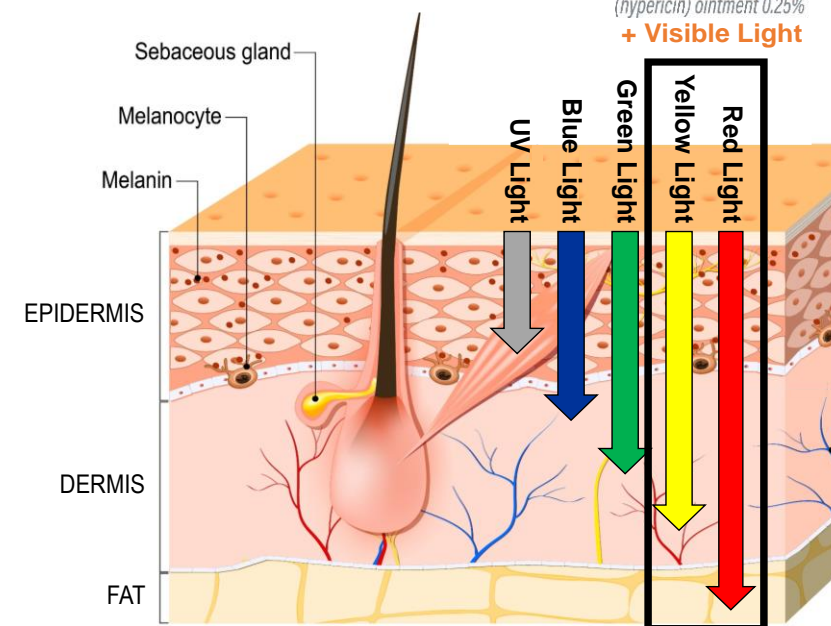
- **Minimal reported adverse events**
  - Other CTCL treatments characterized by acute and chronic side effects
- **Uses visible fluorescent light**
  - **Not** carcinogenic unlike other UV phototherapy or photodynamic therapy

**HyBryte™**  
(hypericin) ointment 0.25%  
+ Visible Light

## ➤ US/EU orphan designations; US fast track status

## ➤ Rapid treatment response

- Phase 3 data demonstrates **statistically significant efficacy as early as 6 weeks** with improved responses through 12 weeks (40%) and 18 weeks (49%)
  - Most early-stage CTCL treatments require *at least 12 months* to observe a statistically significant response
- **Effective against patch and deeper plaque lesions**
  - Other early-stage CTCL treatments known to be useful against patches but lacking in efficacy against plaques



# HyBryte™ – Phase 3 Clinical Trial

referred to as the “FLASH” (Fluorescent Light And Synthetic Hypericin) Study

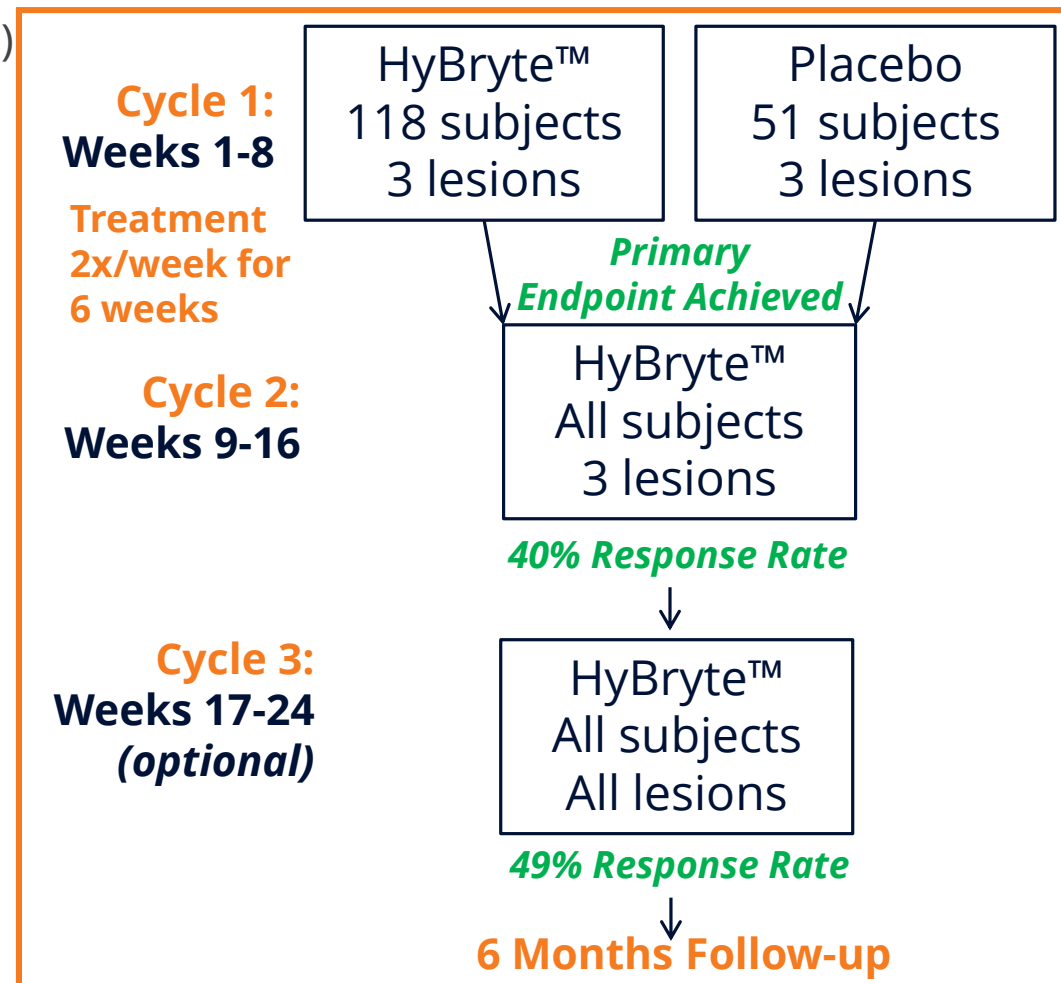
(*JAMA Dermatology*. Published online July 20, 2022. doi:10.1001/jamadermatol.2022.2749)

## ➤ Highly powered, double-blind, placebo-controlled, randomized

- Randomized 2:1 (HyBryte™ [synthetic hypericin 0.25%] : placebo)
- **Cycle 1 complete: Primary Endpoint (response rate) statistically significant (p=0.04)**
  - **Primary endpoint:** Percent of patients achieving  $\geq 50\%$  cumulative reduction as assessed by Composite Assessment of Index Lesion Severity (CAILS) score for 3 index lesions at the end Cycle 1 (week 8)
- **Cycle 2 complete: Statistically significant improvement in treatment response of 40% (p<0.0001)**
- Statistically significant improvement in **BOTH patch and plaque lesion responses** after Cycle 2
  - **Plaque: 42% improvement (p<0.0001)**
  - **Patch: 37% improvement (p=0.0009)**
- **Optional Cycle 3 complete: Statistically significant improvement in treatment response of 49% (p<0.0001)**

## ➤ Secondary Endpoints

- Treatment response (including duration), degree of improvement, time to relapse and safety



# HyBryte™ – Development Status

- Positive pivotal Phase 3 FLASH study successfully completed in 2020 to support potential US marketing approval
  - Largest double-blind, randomized, placebo-controlled clinical trial ever conducted in CTCL population
- HyBryte™ new drug application (NDA) for early-stage CTCL submitted to FDA Dec. 2022
- FDA NDA Refusal to File (RTF) letter received Feb. 2023
- Second confirmatory Phase 3 study of similar design but longer comparative treatment duration than FLASH study required
  - FDA thinking had evolved since protocol discussions for FLASH study
- Actively engaged in discussions with both FDA and EMA to obtain agreement on a feasible design for a 2<sup>nd</sup> study that would be highly executable
  - Agreement expected 1H2024
- Phase 3 confirmatory study to be initiated in 2H2024

# Significant opportunity for improvement to current treatment paradigm in early stage CTCL

## Early Stage CTCL Treatment Paradigm



### Topical steroids

(Typically pre-Dx, not often efficacious; not approved for CTCL)

**HyBryte**

(hypericin sodium) ointment 0.25%

(Approved in CTCL 1<sup>st</sup> line)<sup>1</sup>

**Mechlorethamine**  
(2<sup>nd</sup> line)

**nbUVB<sup>2</sup>**  
(Not approved  
for CTCL)

**Topical  
Retinoids**  
(2<sup>nd</sup> line)

**PUVA<sup>3</sup>**  
(Not approved  
for CTCL)

## Current Treatment Landscape

- Because of chronic nature of early stage CTCL and long-term treatment cycles, clinicians choose therapies with better safety profiles first and foremost
- Clinicians see critical need for additional treatment options with fewer side effects
- NB UVB and PUVA are not targeted therapies and have serious side effects with extended use (e.g., melanoma)
- NB UVB is used on 20%-50% of early-stage CTCL patients, despite not being approved

*"[We] only have two FDA approved drugs with lots of side effects."* — Specialist Dermatologist at Center of Excellence

Empiric Tx

CTCL Dx Tx

# HyBryte™ a Significant Commercial Opportunity Addressing a Clear Unmet Need



## Unmet Need

- Clinicians see need for additional treatment options with fewer side effects
- Most patients cycle through several treatments over course of their disease
- Chronic nature of early stage CTCL and dissatisfaction with current therapies provides opportunity for HyBryte™



## Positive Feedback

- Derms like *efficacy* of HyBryte™; rapid response with equal effect on both patches and plaques
- Derms like *safety* of HyBryte™; use of safe, visible light vs. UV light exposure
- 4 of 5 Derms likely to prescribe HyBryte™



## Efficient Commercialization

- Planned launch focused on high volume CTCL specialists
- Targeted sales force of ~20 reps; reaching >80% of high volume prescribers
- Partnership with medical device company, Daavlin, allows convenient end-to-end business solution for companion light unit to customers



## Sales Potential

- Treatment will not have large financial impact on payers; low/no barriers to access as reimbursement can occur under existing CPT code
- Competing 2<sup>nd</sup> line products with inferior profiles have achieved similar sales
- Life cycle management upside, with potential to transition to home use setting

**HyBryte**  
(hypericin sodium) ointment 0.25%

**>\$90M**  
**US Annual**  
**Net Sales**

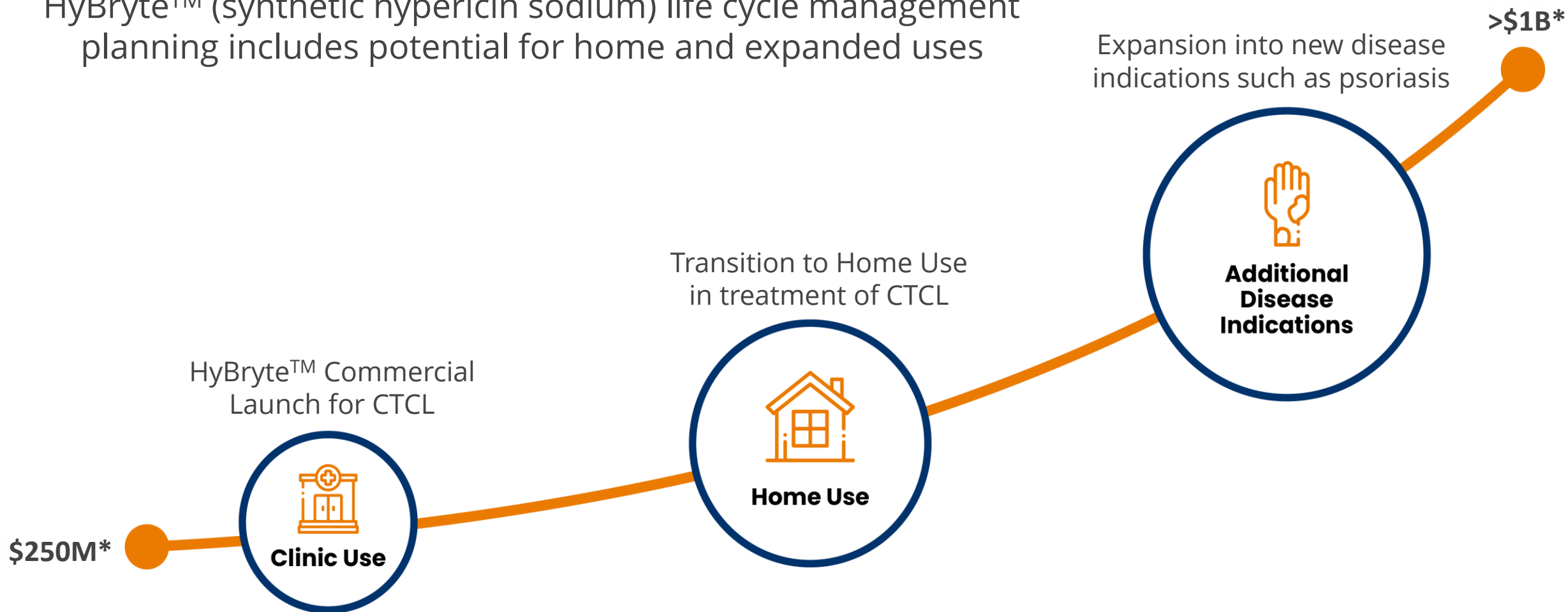
# Psoriasis and SGX302 (Synthetic Hypericin)

- **Caused by dysregulated T-cells**
  - Affects 60-125 Million people worldwide
  - Affects 8 Million people in the US
- **SGX302 – visible light activated photodynamic therapy**
  - Same active ingredient as HyBryte™ but may involve a new formulation
  - Focused on mild-moderate patients, especially the majority with mild-moderate plaque disease
  - Positive Phase 1/2 pilot study complete
  - Phase 2a clinical trial ongoing; evaluation of initial five patients (Cohort 1) demonstrated clear biological signal; subsequent four patients (Cohort 2) treated using accelerated light schedule with two patients achieving clinical success (IGA score of 1) during 18 week treatment period
- **Advantages**
  - Other photodynamic/phototherapy approaches in psoriasis use UV light, with significant side effects including risk of cancer
  - Other skin-directed therapies have limited efficacy or can cause localized skin damage
  - Not addressing severe disease (and therefore not competing with biologics or systemic therapies)
  - Potential for in-clinic or at-home use
- **Targeted skin directed therapy for mild-to-moderate psoriasis patients (~70% of psoriasis patients); underserved market opportunity**



# HyBryte™ Life Cycle Management

HyBryte™ (synthetic hypericin sodium) life cycle management planning includes potential for home and expanded uses



\* Total addressable global market

# 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*

Product Candidates (FDA Animal Rule)* **	Proof-of-Concept	IND	Phase 1	Phase 2/3	BLA Review	Market
<b>RiVax</b> <sup>®</sup> + ThermoVax <sup>®</sup> – Vaccine Ricin Toxin Pre-Exposure	ORPHAN & FAST TRACK DESIGNATION			NIH Contract Awards of <b>\$30M</b> to date; positive preclinical and clinical data		
<b>SuVax</b> <sup>™</sup> / <b>MarVax</b> <sup>™</sup> + ThermoVax <sup>®</sup> – Filovirus Vaccines		NIH Grant Subaward of <b>\$700,000</b> to date; positive preclinical data				
<b>CiVax</b> <sup>™</sup> + ThermoVax <sup>®</sup> – Vaccine COVID-19		NIH Grant Award of <b>\$1.5M</b> to date; positive preclinical data				

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

\* Anticipated event and timing subject to COVID-19 disruption

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

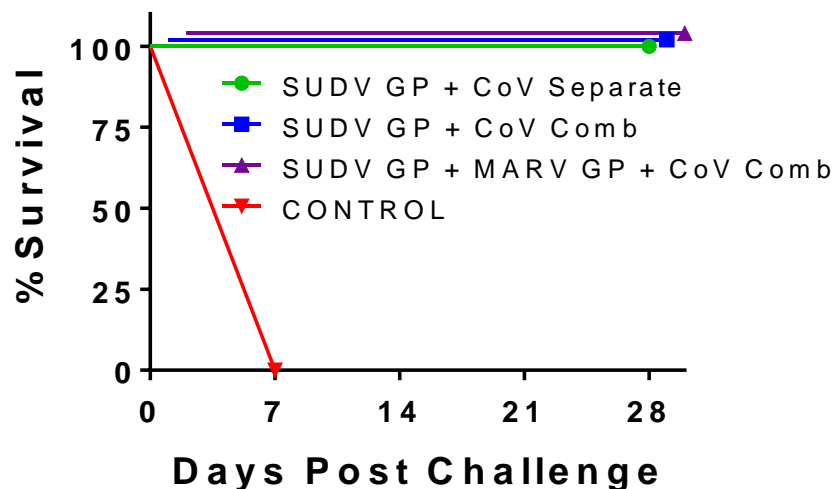
### ***With FDA MCM approvals, potential to be awarded:***

- **Up to 3 Priority Review Vouchers (PRVs have sold for ~\$100 million)**  
to be used for future programs or sold, and/or
- **Government Procurement Contracts**  
for supplying strategic national stockpile

# SuVax™ / MarVax™ – Filovirus Vaccine Candidates

Heat-stable single-vial bivalent  
SUDV + MARV vaccine provided  
**100% protection** against  
**SUDV and MARV** challenge:  
Published in Vaccine

**SUDV Challenge  
at Week 12**



## Market Opportunity

- Filovirus infections (*Zaire ebolavirus*, *Sudan ebolavirus*, *Marburg marburgvirus*) are deadly; only Zaire strain vaccines are available and requires  $\leq -60^{\circ}\text{C}$  shipping/storage
- Disease-endemic areas benefit from ability to avoid cold-chain distribution
- Government has placed priority on development activities, with *Marburg marburgvirus* and *Sudan ebolavirus* areas of unmet medical need
- Potential for SuVax™/MarVax™ to qualify for Priority Review Vouchers

## Development Status

- Collaboration with the University of Hawai'i at Mānoa, under NIH grant
- Demonstration of efficacy in NHPs
- Bi- and Tri-valent mixtures feasible
- Stability of at least 2 years at  $40^{\circ}\text{C}/104^{\circ}\text{F}$  demonstrated.

# Experienced Management and Board of Directors

<p>Christopher J. Schaber, PhD Chairman, President &amp; CEO</p>	<ul style="list-style-type: none"> <li>• 30 years of experience</li> <li>• Discovery Laboratories (COO)</li> <li>• Acute Therapeutics (Co-Founder)</li> <li>• Ohmeda Pharmaceuticals</li> <li>• The Liposome Company</li> <li>• Wyeth Ayerst</li> </ul>	<p>Gregg Lapointe, CPA, MBA</p>	<ul style="list-style-type: none"> <li>• 30 years of experience</li> <li>• Cerium Pharmaceuticals (CEO)</li> <li>• Formerly of Sigma-Tau Pharmaceuticals, AstenJohnson, PricewaterhouseCoopers</li> </ul>
<p>Richard Straube, MD Chief Medical Officer</p>	<ul style="list-style-type: none"> <li>• 35 years of experience</li> <li>• Stealth Peptides Inc.</li> <li>• INO Therapeutics</li> <li>• Ohmeda Pharmaceuticals</li> <li>• Centocor</li> </ul>	<p>Diane Parks</p>	<ul style="list-style-type: none"> <li>• 30 years of experience</li> <li>• Formerly of Kite Pharma, Pharmacyclics, Amgen, Genentech</li> </ul>
<p>Oreola Donini, PhD Chief Scientific Officer</p>	<ul style="list-style-type: none"> <li>• 20 years of experience</li> <li>• Inimex Pharmaceuticals</li> <li>• ESSA Pharma, Inc.</li> <li>• Kinetek Pharmaceuticals</li> </ul>	<p>Robert Rubin, MD</p>	<ul style="list-style-type: none"> <li>• 40 years of experience</li> <li>• Georgetown School of Medicine</li> <li>• Formerly of The Lewin Group</li> <li>• Former U.S. Assistant Surgeon General</li> </ul>
<p>Jonathan Guarino, CPA, CGMA Chief Financial Officer</p>	<ul style="list-style-type: none"> <li>• 25 years of experience</li> <li>• Hepion Pharmaceuticals, Inc.</li> <li>• Covance, Inc.</li> <li>• BlackRock, Inc.</li> <li>• Barnes &amp; Noble, Inc.</li> <li>• PricewaterhouseCoopers LLP</li> </ul>	<p>Jerome Zeldis, MD, PhD</p>	<ul style="list-style-type: none"> <li>• 35 years of experience</li> <li>• Formerly of Celgene Corporation (CMO), Sandoz, Janssen Research Institute, Sorrento, Celularity, NexImmune</li> </ul>

# In Summary

- Robust pipeline consisting of multiple fast track and/or orphan designated products, with potential for significant commercial returns of ~\$2B in global annual sales
- Late clinical-stage assets, one with successful Phase 3 data readout
  - **Cutaneous T-cell lymphoma (HyBryte™ or SGX301)**
    - **Positive statistically significant results achieved in first Phase 3 study**; published JAMA Dermatology
    - Actively engaged in FDA and EMA discussions regarding feasible trial design for second confirmatory Phase 3 study
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$250M**
  - **Psoriasis (SGX302)**
    - **Positive and statistically significant results achieved in Phase 1/2 proof of concept (POC) study**
    - Phase 2a study in mild-to-moderate psoriasis **ongoing; clinical success achieved in 2 of 4 Cohort 2 patients**
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$1B**
  - **Behçet's disease (SGX945)**
    - Phase 2a study in aphthous ulcers in Behçet's Disease; **FDA IND, protocol clearance and fast track received**
    - Significant commercial opportunity in area of unmet medical need; **estimated global market potential >\$200M**
- Collaborations with biotech, academia and government agencies
- Non-dilutive government funding helps cover operating expenses
  - NIH grant awards supporting vaccine development; potential for up to 3 Priority Review Vouchers (PRVs)
- Experienced management team and renowned advisors with record of success

**HyBryte**

(hypericin sodium) ointment 0.25%

# Thank you

Follow us on:

 [facebook.com/soligenix/](https://facebook.com/soligenix/)

 [youtube.com/c/SoligenixInc](https://youtube.com/c/SoligenixInc)

 [twitter.com/Soligenix\\_Inc](https://twitter.com/Soligenix_Inc)

 [linkedin.com/company/soligenix-inc/](https://linkedin.com/company/soligenix-inc/)



[www.soligenix.com](https://www.soligenix.com)

NASDAQ: SNGX