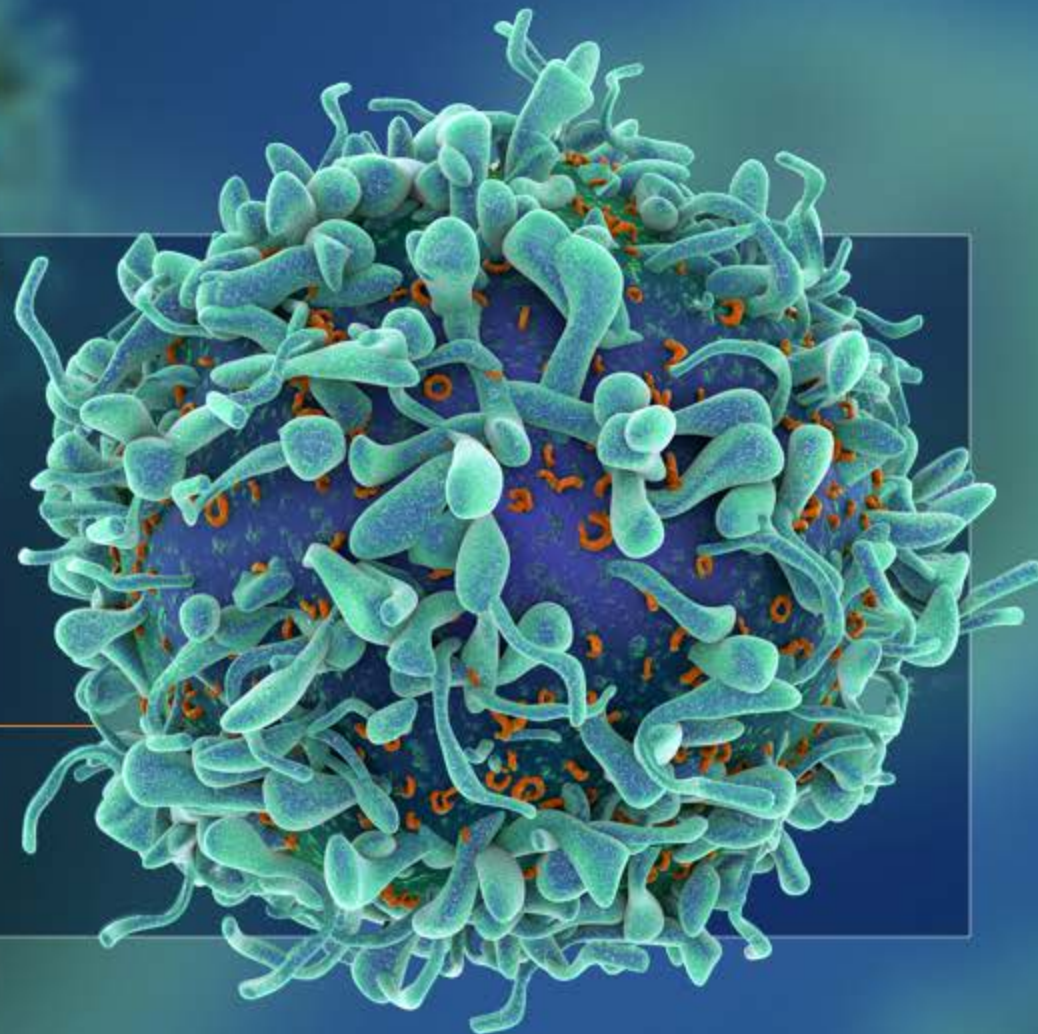




# COVID-19 Landscape and Applications

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**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.

# Agenda

- Corporate overview Dr. Christopher Schaber, President & CEO, Soligenix
- COVID-19 and vaccine overview Dr. Axel Lehrer, Associate Professor, University of Hawaii
- CiVax program overview Dr. Oreola Donini, CSO, Soligenix
- Dusquetide in COVID-19 Dr. Oreola Donini
- COVID-19 vaccine market Daniel Ring, MBA, Vice President, Business Development & Strategic Planning, Soligenix
- Closing summary Dr. Christopher Schaber
- Question and Answer All

# Christopher Schaber, PhD

- **Chairman, President & CEO**
  
- **30 years of broad R&D and operational experience across pharmaceutical and biotech industry**
  - **Discovery Laboratories (COO)**
  - **Acute Therapeutics (Co-Founder)**
  - **Ohmeda Pharmaceuticals**
  - **The Liposome Company**
  - **Wyeth Ayerst**
  
- **Detailed bio at: <https://www.soligenix.com/about/executive-team/>**

# 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

# Development Pipeline – Rare Diseases

## Specialized BioTherapeutics

Product Candidates	Preclinical	Phase 1	Phase 2	Phase 3	Market
<b>SGX301</b> Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION				Positive primary + Cycle 2 results
<b>SGX942</b> Oral Mucositis in Head & Neck Cancer	FAST TRACK DESIGNATION				Enrollment complete; Ph. 3 data <b>4Q 2020*</b>
<b>SGX203</b> Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION				Initiation contingent upon additional funding and/or partnership*
<b>SGX201</b> 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
<b>RiVax®</b> + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN & FAST TRACK DESIGNATION			NIH Contract Award of <b>\$21.2M</b>	
<b>CiVax™</b> + ThermoVax® – COVID-19 Vaccine		Collaboration with the University of Hawai'i at Mānoa			
<b>SGX943</b> – Therapeutic Emerging Infectious Disease	FAST TRACK	USG awards of <b>\$900,000</b> to date; positive proof of concept preclinical data			
<b>ThermoVax®</b> – Vaccine Heat Stabilization Technology		Ebola/Marburg: <b>\$700,000</b> Grant Subaward;			

 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

# Axel Lehrer, PhD

- **Associate Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Mānoa**
- **18 years of experience in vaccine research and development**
  - Previous research in vaccine R&D with filoviruses (e.g., Ebola) and flaviviruses (i.e., Zika virus, Tick-borne encephalitis (TBE) virus, West Nile virus and Dengue virus)
  - Developed protein expression methodologies for vaccine manufacture

# COVID-19: Disease Background

- **Respiratory illness caused by SARS-CoV-2 virus**
  - **Droplet transmission is believed to be the major mode of transmission in enclosed spaces**
  - **Spike protein (trimeric glycoprotein on viral surface) is key to viral entry, utilizing the human ACE2 receptor, which is prevalent in the respiratory tract,**
    - **Targeting of ACE2 may explain some of the varied disease presentations in COVID-19**
  
- **Inflammatory response drives mortality**
  - **Response to viral infection engages the innate immune response – including BOTH the anti-infective and the inflammatory disease arms**
    - **Inflammation may also arise from the adaptive immune cells (B/T cells)**
  - **Inflammatory response enhances damage to the lung (or other areas where the virus is present)**
    - **Causes acute respiratory distress which is the primary driver of mortality**



# COVID-19: Treatment Background

- **Treatment options focused on “severe” disease**
  - **Remdesivir shown to decrease length of hospital stay, but not to increase survival (yet)**
    - **Anti-viral treatment administered IV and likely primarily targets systemic viral circulation**
  - **Dexamethasone may decrease mortality**
    - **Anti-inflammatory steroid which may also increase the risk of secondary bacterial infections**
- **Mild to moderate patients, although hospitalized, are treated with oxygen therapy but there are no approved, standard treatments**
  - **No treatments shown to prevent progression to more severe disease**
- **There are no treatments for patients not requiring hospitalization**

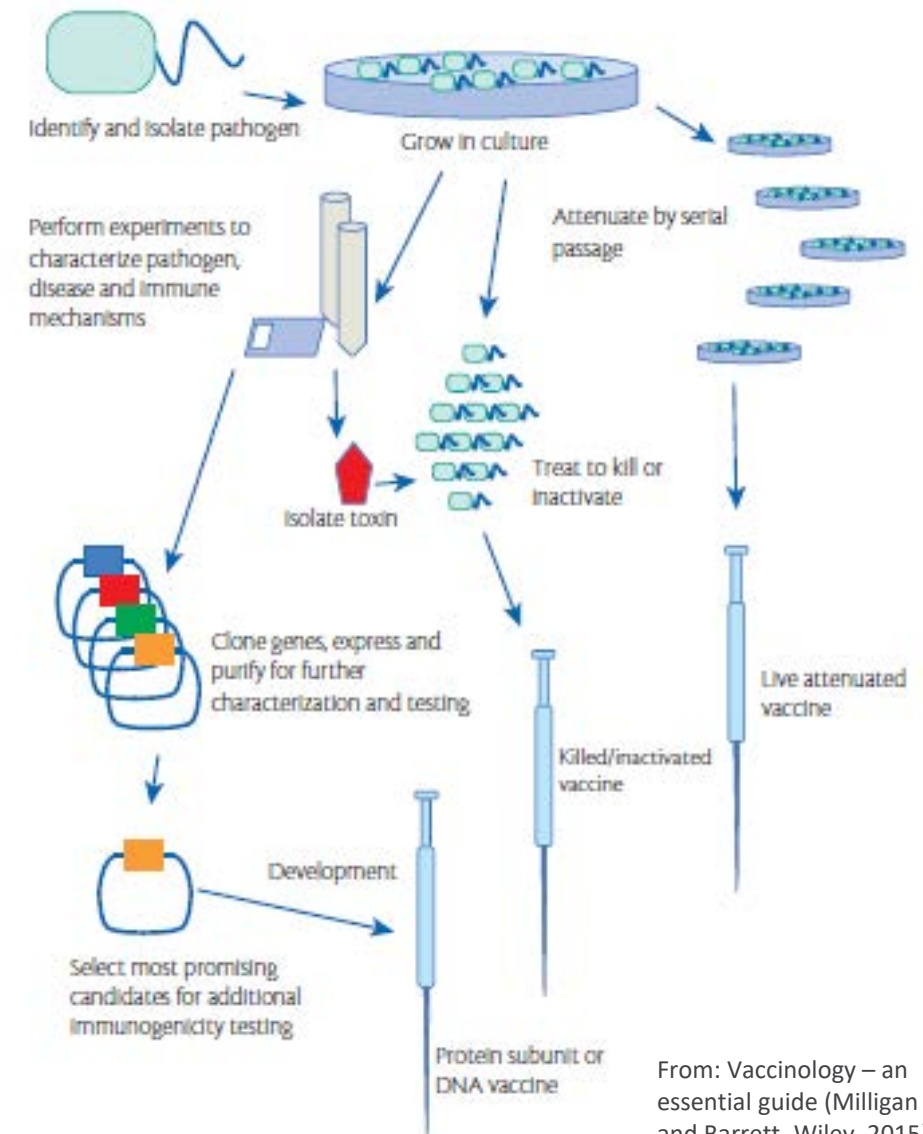
# COVID-19: Vaccine Background

- **Many vaccines in development – utilizing different vaccine platforms**
  - **Different platforms may be used to target different patient populations**
    - **Mainly driven by safety profile**
  - **Different platforms have different logistical requirements**
    - **Storage/distribution requirements – ambient temperature, refrigeration, freezing at -20°C, -70°C**
    - **Dosage requirements – most believed to require at least 2 doses to raise the required immunity**
    - **Manufacturing requirements – types of facilities differ according to vaccine platform**
- **Durability of immune responses unknown**
  - **Will there be a requirement for yearly/seasonal vaccination as with flu?**
- **Sufficiency of immune response (e.g., efficacy) unknown but Phase 3 studies correlating efficacy with immunogenicity measures are ongoing for candidates based on several platforms**

# Vaccine Platforms

## ➤ Development Platforms:

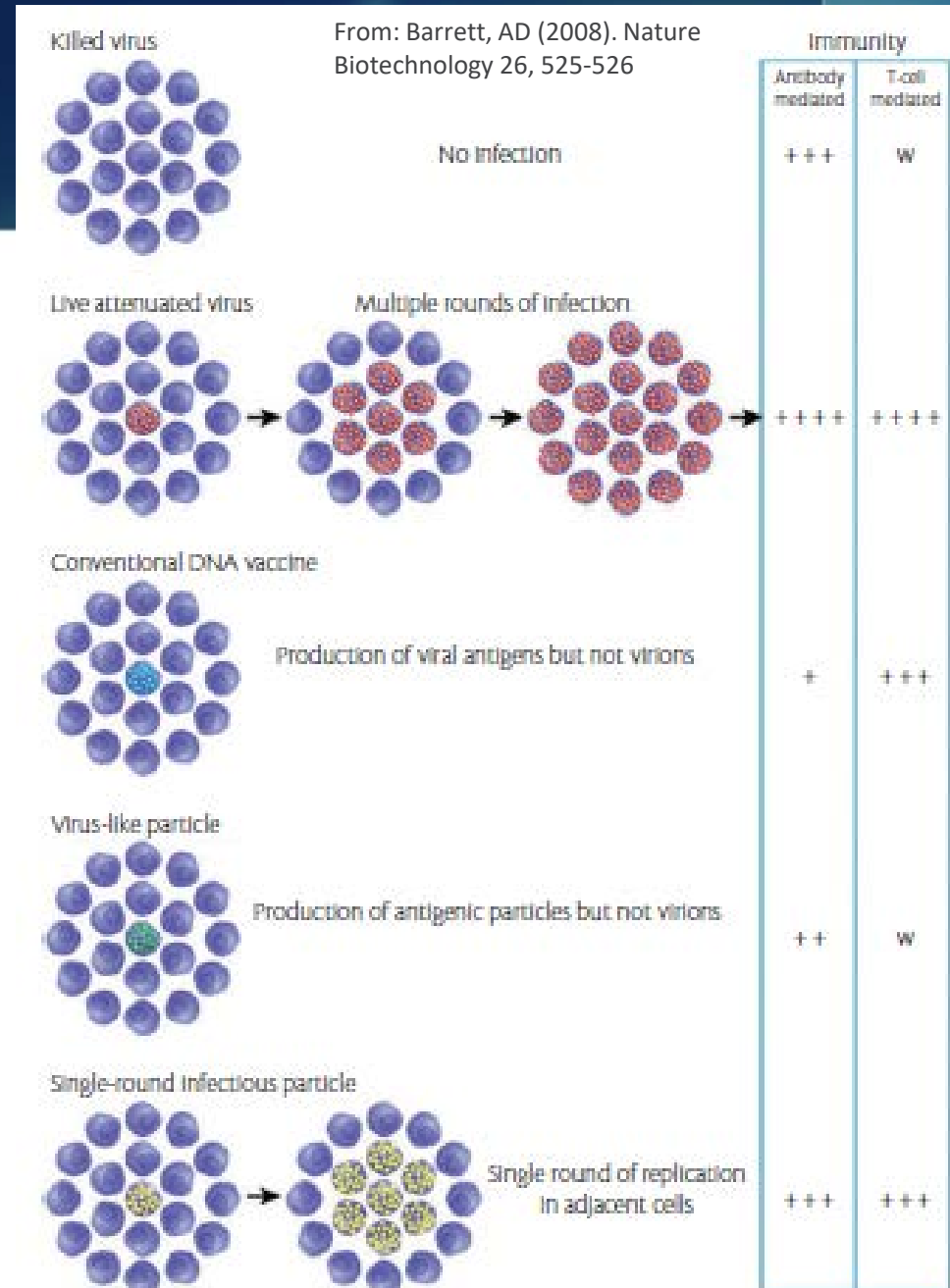
- Conventional (live attenuated, inactivated virus)
- Subunit (conventional or recombinant)
- Recombinant (genetic expression of antigen):
  - Viral vectors (replicated limited or incompetent)
    - Adenovirus, chimp adenovirus, VSV, measles virus etc.
  - RNA
  - DNA



From: Vaccinology – an essential guide (Milligan and Barrett, Wiley, 2015)

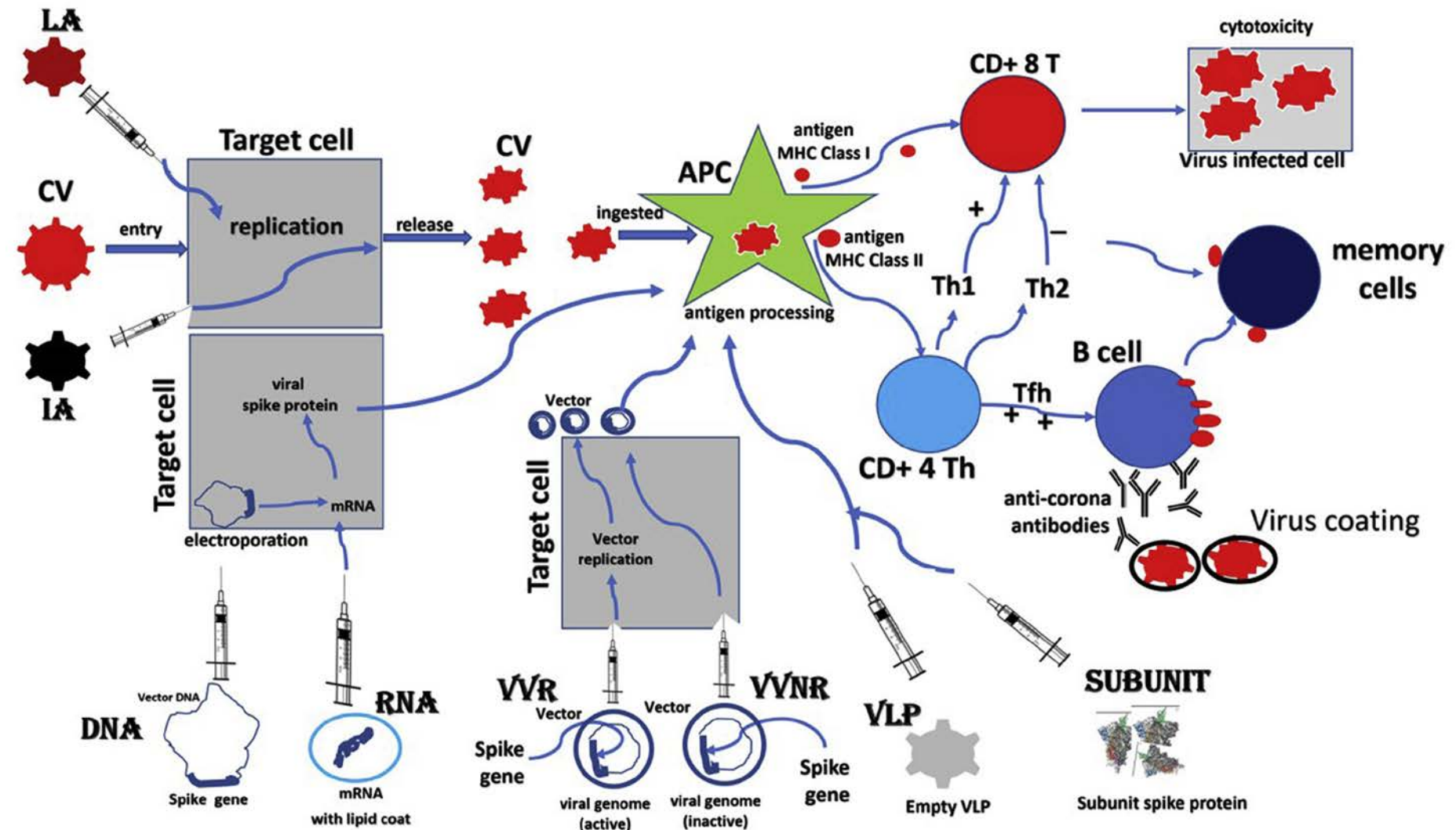
# Immune Response

- Different platforms modulate different immune responses
- For COVID-19, emphasis has been placed on:
  - Total antibody response
    - Can be raised by isolated pieces of the virus (e.g., pieces of protein)
    - Antibodies to Receptor-binding domain are believed to inhibit viral entry
  - Th1 balanced response
  - Neutralizing antibody response
  - Cell mediated (T-cell) response
    - Often associated with having intracellular expression of viruses
    - Required for potent memory effect and viral clearance



# Immune Response

- Live-attenuated vaccine (LA)
- Inactivated vaccine (IA)
- DNA vaccine (DNA)
- RNA vaccine (RNA)
- Viral vector replicating vaccine (VVR)
- Viral vector nonreplicating (VVNR)
- Virus-like particles (VLP)
- Subunit vaccine (Subunit)



# Vaccine Candidates

<b>Platform</b>	<b>Pre-clinical</b>	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>
<b>Inactivated</b>	9		2 ?	3
<b>live attenuated</b>	4			
<b>protein subunits</b>	61	5	4 ?	
<b>VLP</b>	14	1		
<b>DNA</b>	12		4 ?	
<b>RNA</b>	21	2	2 ?	2 ?
<b>non-replicating viral vector</b>	20	1	3 ?	1
<b>replicating viral vector</b>	18			

Source: Milken Institute COVID-19 tracker

Accessed 09/07/2020

# Oreola Donini, PhD

- **Senior Vice-President & Chief Scientific Officer**
- **20 years industry experience**
  - Inimex Pharmaceuticals
  - ESSA Pharma, Inc.
  - Kinetek Pharmaceuticals
- **Focused preclinical and early clinical development**
  - Lead programs in early manufacturing, GLP toxicology and pharmacology
  - Ricin toxin vaccine
  - Host innate immune modulator with anti-infective and anti-inflammatory activity
- **Detailed bio at: <https://www.soligenix.com/about/executive-team/>**

# Anti-viral Glycoprotein Vaccine Platform

- **Antibody and cell-mediated responses preferred**
- **Viral antigens are often multimeric viral surface glycoproteins**
- **Platform developed in collaboration with University of Hawaii**
  - **Insect cell expression system to produce multimeric proteins with stable glycosylation patterns**
  - **CoVaccine HT™ adjuvant (licensed from BTG-Boston Scientific) stimulates humoral and cell mediated immunity**
  - **Thermostabilization platform to enable co-lyophilized formulations**
- **Vaccines are individually lyophilized in vials and only need to be reconstituted with sterile water for injection immediately prior to use**
  - **At least 12 weeks stability at 40°C (104°F) demonstrated**

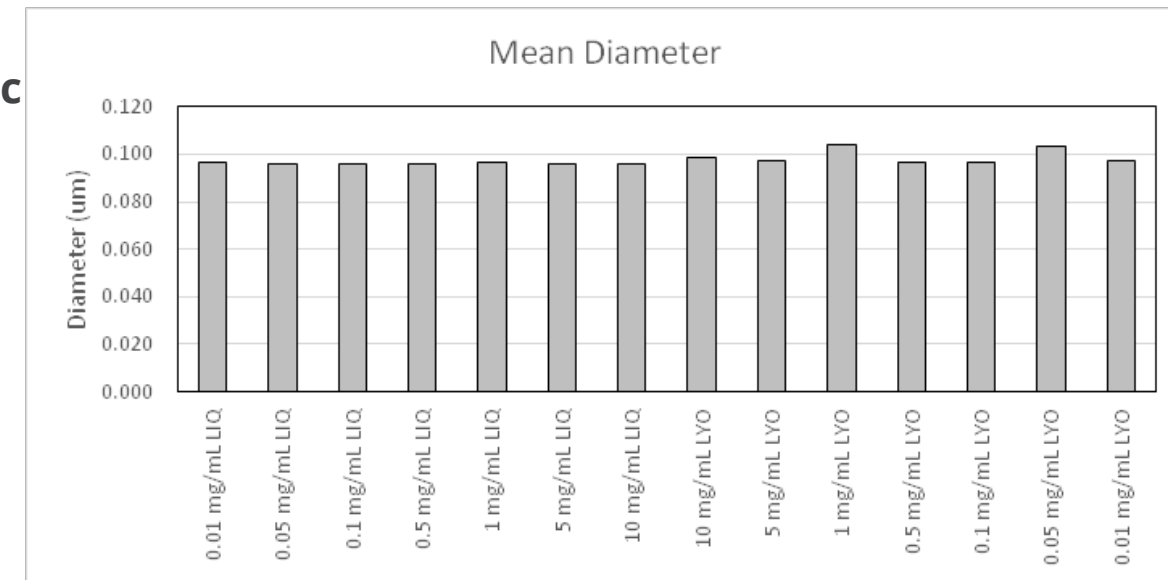


# Soligenix: Anti-Viral Protein Vaccines

- **Gold standard vaccine platform for safety**
  - Equally applicable to older populations and immunocompromised populations, allowing widest possible application
- **Antigen production**
  - Stably transformed insect S2 expression system produces stable glycosylation combined with protein-specific affinity chromatography
  - Expression system previously used in clinical programs for West Nile and Dengue virus vaccines
- **Potency driven by characteristics of the adjuvant**
  - Alum stimulates humoral immunity but not cell mediated immunity (anti-ricin toxin vaccine; RiVax<sup>®</sup>)
  - Licensed CoVaccine HT<sup>™</sup> which stimulates BOTH antibody and cell-mediated immunity (*licensed from BTG (Boston Scientific)*)
- **ThermoVax<sup>®</sup> – Soligenix’s thermostabilization platform**
  - Unique, patented method to thermostabilize alum (previously problematic)
  - **Proprietary method to stabilize nano-emulsions (like CoVaccine HT<sup>™</sup>)** (applicable to viral vaccines against filoviruses, coronaviruses and flu)

# CoVaccine HT™ – Nanoemulsion adjuvant

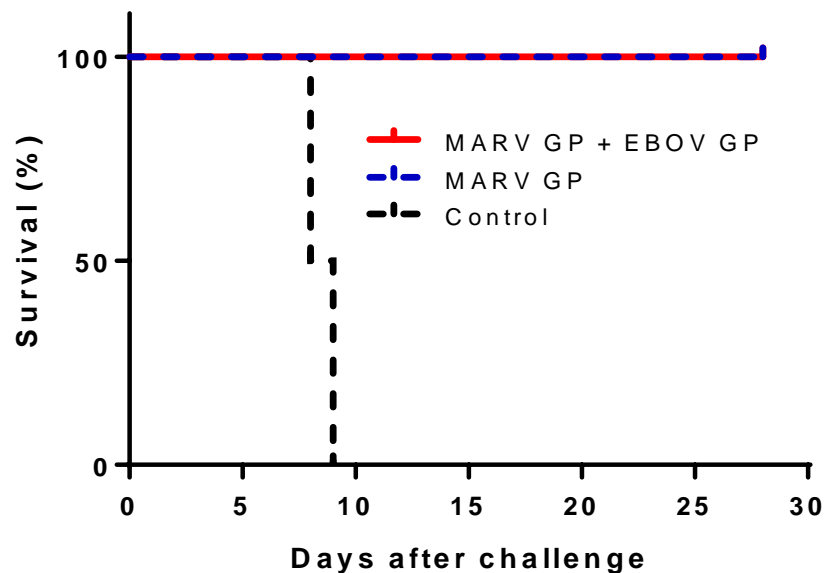
- **Safety demonstrated in Phase 1 and Phase 2 clinical studies in a non-infectious disease context**
  - MTD 10 mg/dose
- **Nonclinical efficacy data in the context of viral vaccines (e.g., EBOV, SUDV, MARV, Zika, Tick borne encephalitis)**
  - Broad applicability to viral disease (including pandemic flu and coronaviruses)
  - Strong immunogenicity in COVID-19 prototype vaccine
  - Demonstrated in mice and non-human primates
- **Demonstrated stability and potency after lyophilization**
  - Maintain critical particle size after reconstitution
  - Maintains potency after reconstitution



# TriFiloVax – Ebola and Marburg Vaccines

CoVaccine-adjuvanted filovirus vaccine provided **100% protection** in a non-human primate challenge model with *Marburg marburgvirus*

Survival after MARV Challenge



## Market Opportunity

- Filovirus infections (*Sudan virus*, *Marburg virus* and *Ebola virus*) are deadly; only Ebola vaccine is approved and requires  $\leq -60^{\circ}\text{C}$  shipping/storage
- Disease-endemic areas benefit from the ability to avoid cold-chain distribution
- Government has placed priority on development activities, with *Marburg marburgvirus* an area of unmet medical need

## Development Status

- Collaboration with the University of Hawai'i at Mānoa and Hawaii Biotech, under NIH R01 grant
- Demonstration of efficacy in non-human primates
- Bi- and Tri-valent mixtures feasible

# Glycoprotein Platform for COVID-19

Parameter	Filovirus	Coronavirus
Surface glycoprotein antigen	✓ (GP)	✓ (Spike)
Multimeric glycoprotein structure	✓ (trimer+)	✓ (trimer)
Humoral + cell mediated adjuvancy likely required	✓	✓
Cell construct for S2 expression system	✓	✓
Formulation conditions identified	✓	(Pending)
Mouse immunogenicity	✓	✓
Primate immunogenicity	✓	(Pending)
Primate efficacy	✓	(Pending)
Adjuvant human safety	✓	✓
Antigen/vaccine human safety	✗	✗

# CiVax™ Benefits

- CoVaccine shown to elicit **Th1 balanced humoral and cell mediated immunity** with prototype Spike S1 protein antigen in Th2-biased mice, yielding neutralizing antibodies of similar levels to convalescent plasma. Strong antibody response within 14 days of the first vaccination
- **Protein vaccines** avoid the novelty risk of RNA and DNA vaccines (lack of regulatory precedent and vaccine durability), the contra-indications (immunocompromised) and complexity (immunity to vector) of viral vectored vaccines, the reversion risks of attenuated viruses and the potential dose limitations with inactivated viruses
- Spike protein manufacturing uses **stably transformed cell line** with good preliminary yield (sub-cloning not yet conducted) and **immunoaffinity chromatography**
- Vaccination with more complete Spike protein antigen (Spike #13) yields sera antibodies which recognize both the full length spike protein and the isolated RBD domain with high selectivity. Responses confirmed as early as **7 days after the first vaccination**

# CiVax™ Competitive Profile

Parameter / Platform	Protein (Soligenix / UH) *	Protein (NovaVax)	rVSV	chAd (AstraZeneca)	Ad26 (Janssen)	RNA (Moderna/ BioNtech)
Ambient storage	✓	?	✗	✗	✗	✗
Immune compromised populations?	✓	✓	✗	✗	✗	?
Repeat vaccination possible?	✓	✓	✗	Limited	Limited	✓
Single dose regimen?	?	?	?	✗	✗	✗
Simple manufacturing / Scale Out	✓	?	✗	✗	✗	✓
No risk of genomic integration	✓	✓	✗	✗	✗	✓
Single vial formulation	✓	✗	?	✓	✓	✓
Used in other approved vaccines (reduces regulatory risk)	✓	✓	✓ (Ebola)	✗	✓ (Ebola)	✗

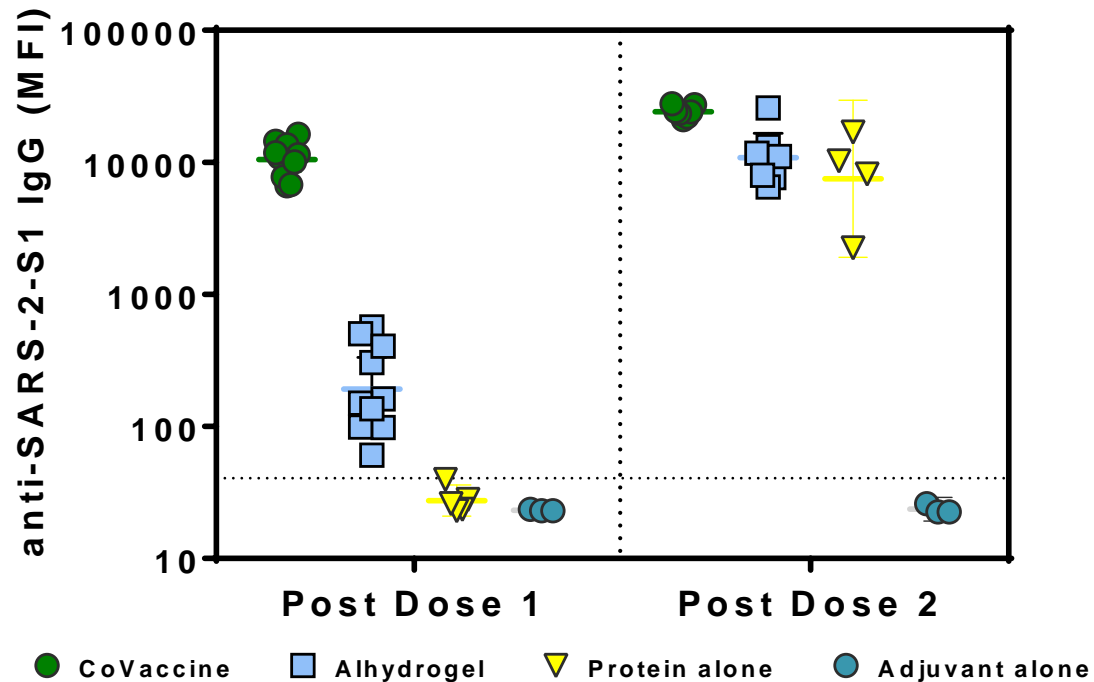
\*uses a stably transformed expression cell line with protein specific affinity purification for antigen production, combined with a novel, clinically proven, adjuvant (CoVaccine), both of which will be combined with GRAS excipients to yield a thermostabilized formulation

# WHO Target Product Profile (TPP)

WHO Preferred Characteristic	CiVax™ TPP
Thermostability (higher temperature preferred)	✓
No contra-indications	✓
Rapid onset of immunity	✓
Single dose regimen (minimal: no more than 2)	✓
Durability of at least 1 year (minimal: At least 6 months)	?
Non-parenteral (minimal: any route)	✓ (Needle free is possible, parenteral administration for first line product)
Co-administration with other vaccines in long term	✓

# CiVax™ – COVID-19 Vaccine Candidate

Proof of concept study with S1 Spike protein and CoVaccine HT™ adjuvant with **rapid and potent onset of immunogenicity**



## Market Opportunity

- Pandemic response will require many different vaccines to produce adequate coverage worldwide
- Rapid distribution enabled by thermostabilization / avoiding cold-chain
- Government has placed priority on development activities

## Development Status

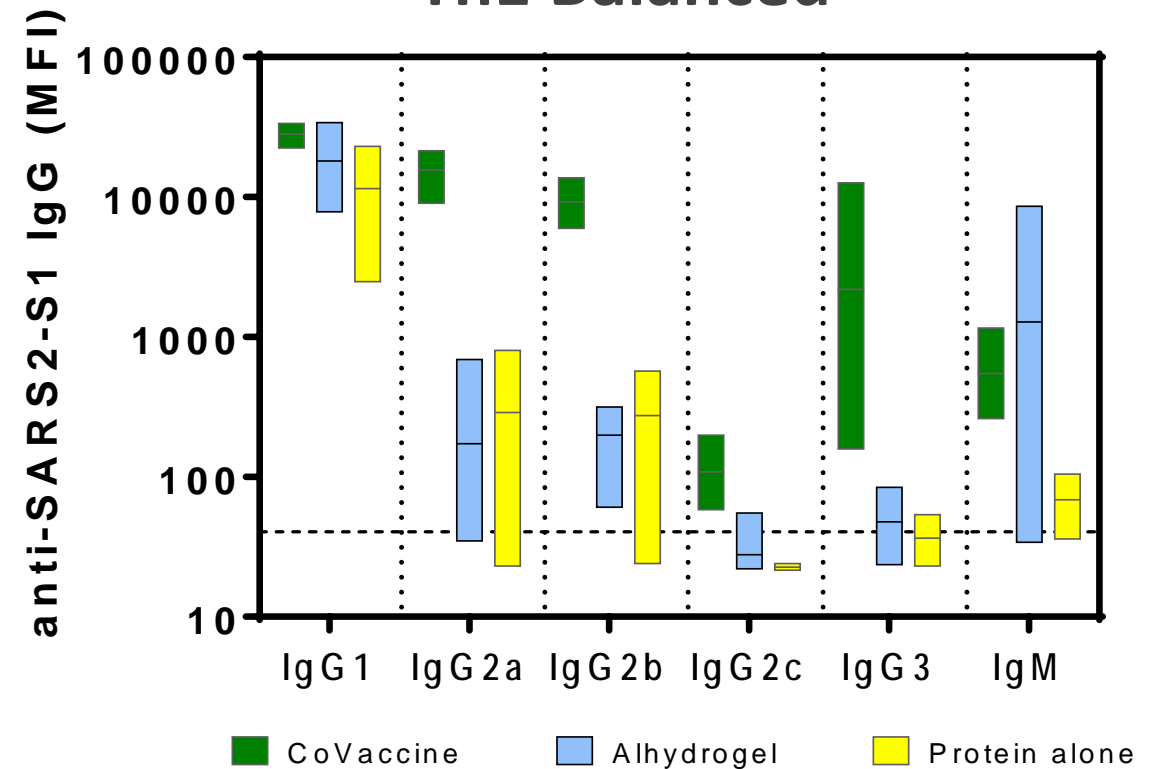
- Proof of concept data in mice:
  - Single dose may be feasible (rapid onset within 7 days)
  - Th1-biased immune response
  - Neutralizing response
- Recombinant insect cell expression for full Spike protein stabilized in pre-fusion complex
- Immunoaffinity chromatography purification developed



# CiVax™ – Proof of Concept Study

- Selective response
- Th1 bias preferred for COVID-19 vaccines
  - **Th1 response demonstrated** (IgG2a and IgG2b subtype responses) in BALB/c (Th2-biased) mice with the use of CoVaccine
  - Superior response to alhydrogel (alum) – shows strong Th2 bias

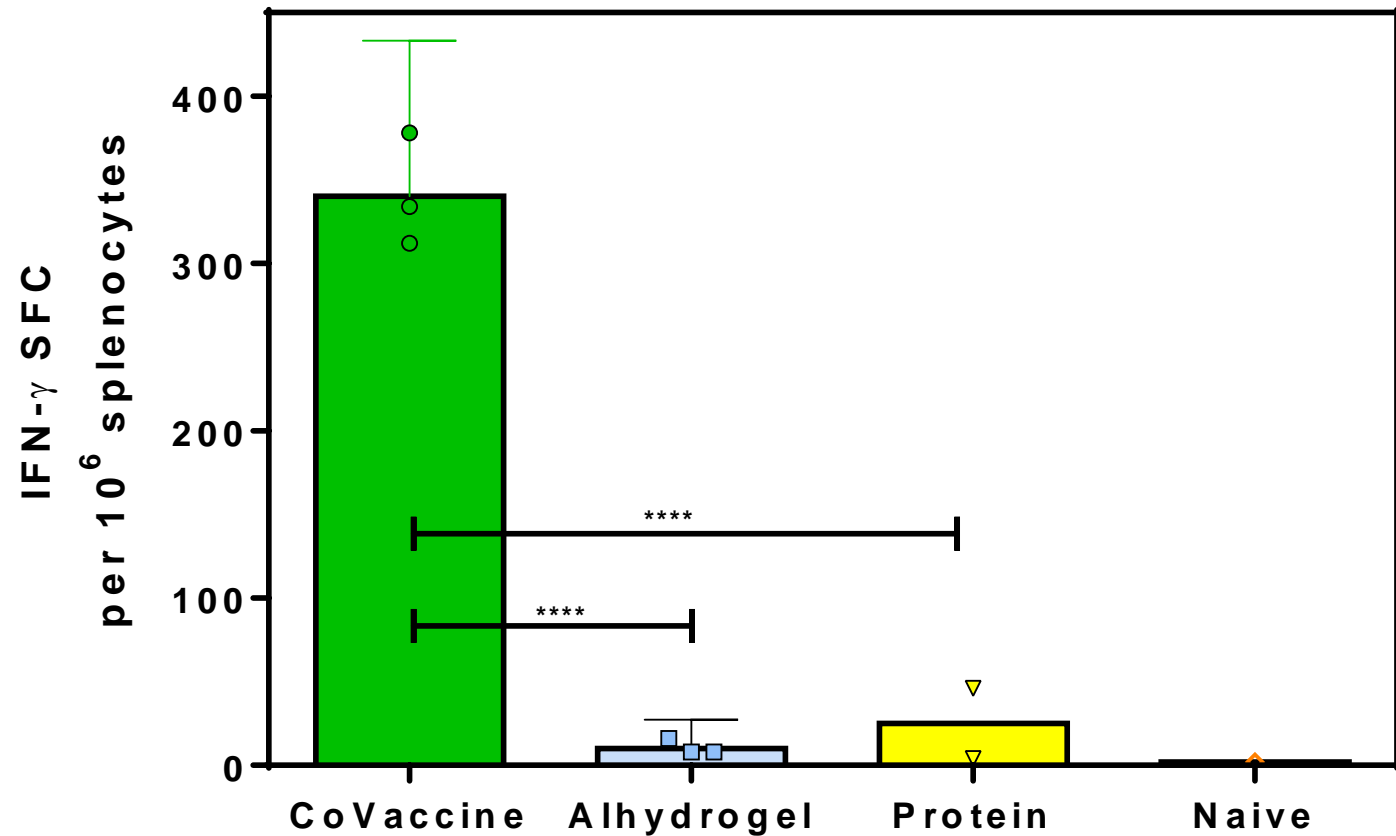
## Isotype Characterization Th1 Balanced



# CiVax™ – Proof of Concept Study

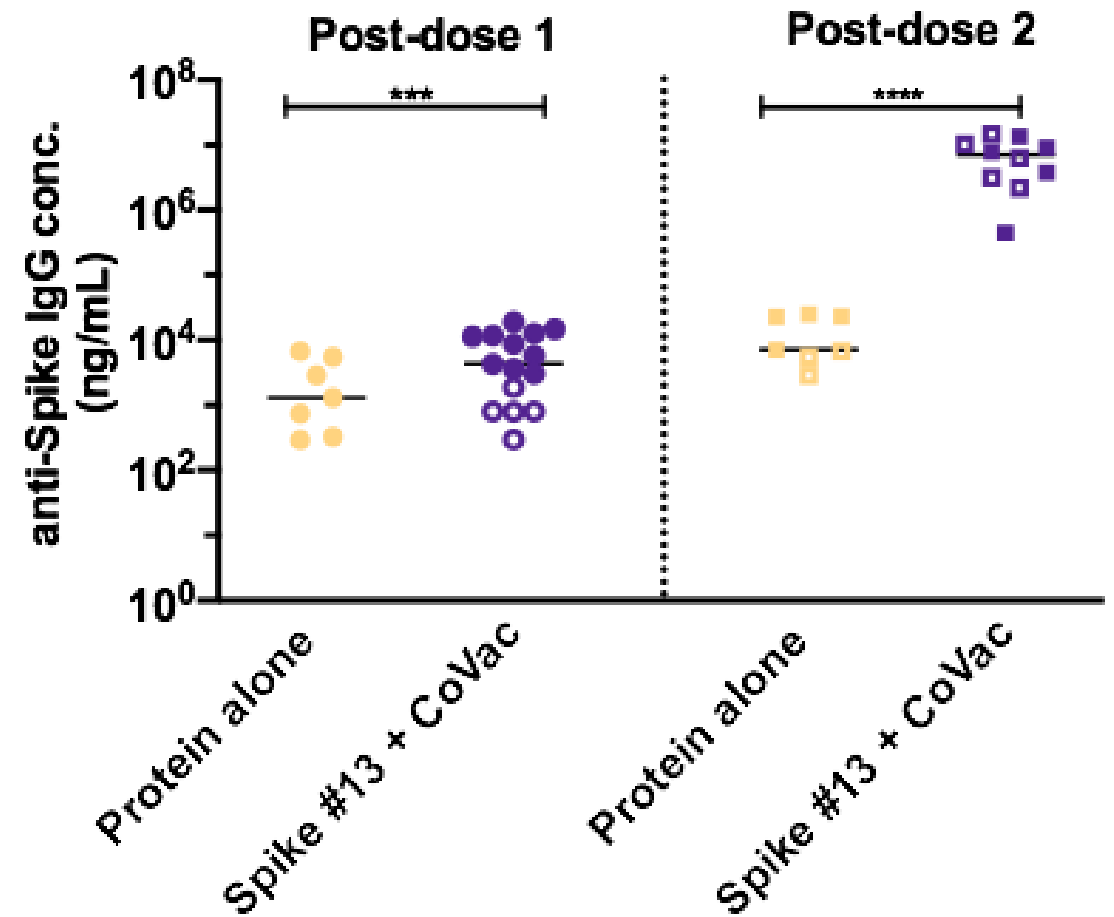
- Strong **neutralizing antibody** responses
  - PRNT90 = 1620
  - **As good as post-convalescent plasma**
- **Enhanced cell mediated immunity**
  - IFN $\gamma$  response indicative of Th1-biased T-cell memory response
- Actively exploring the possibility for **single dose formulation**

## Cell-Mediated Immunity



# CiVax™ – Proprietary Antigen

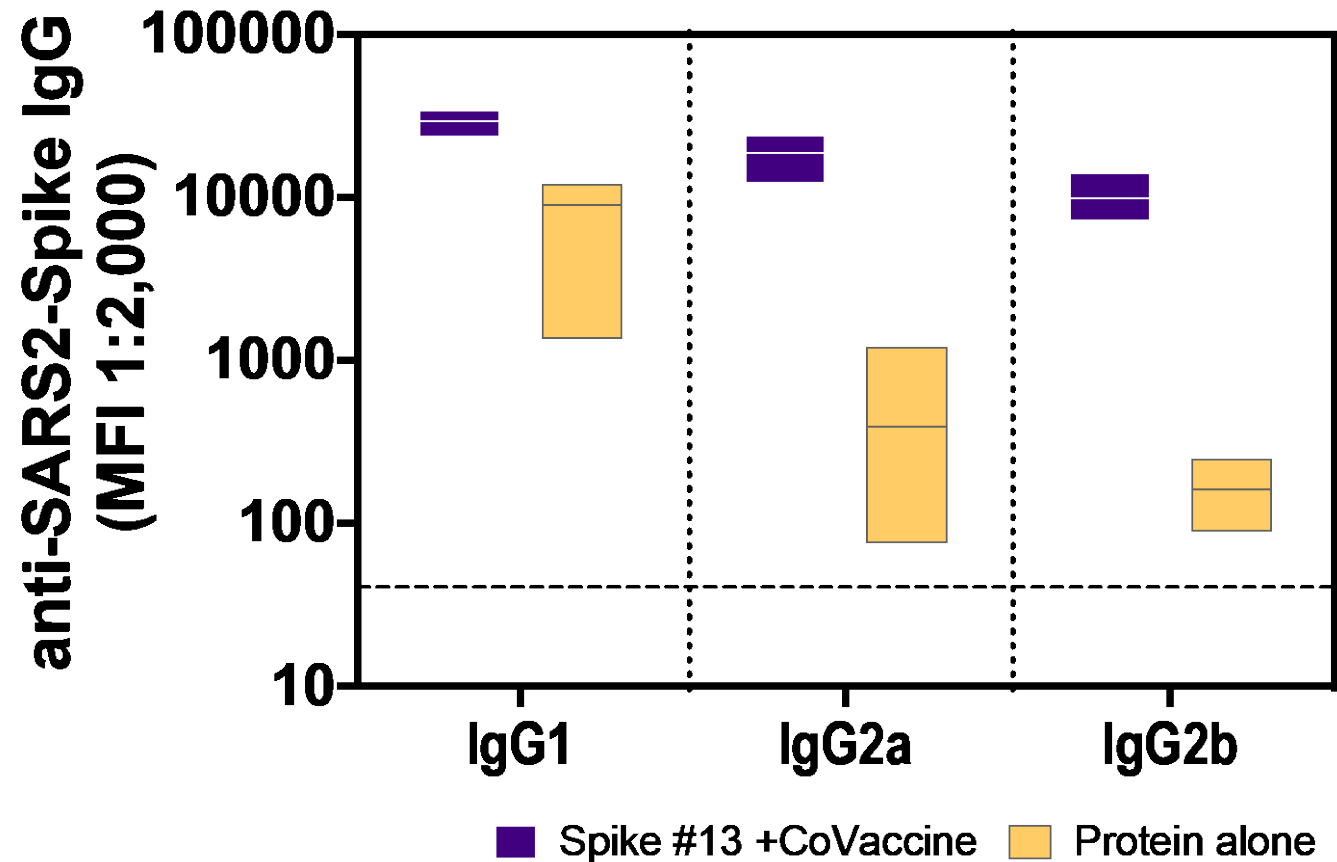
- Expression of full spike protein with mutation to **lock the pre-fusion configuration**
- **Immunoaffinity chromatography** ensures proper / recognizable protein antigen
- Immunogenicity as early as **7 days post-dose**
  - CoVaccine improves kinetics and magnitude of response
- **Rapid development** possible (manufacturing scale up, Phase 1 study initiation) with funding



# CiVax™ – Proprietary Antigen

➤ Strong **Th1 response** in adjuvanted vaccine after 2<sup>nd</sup> dose

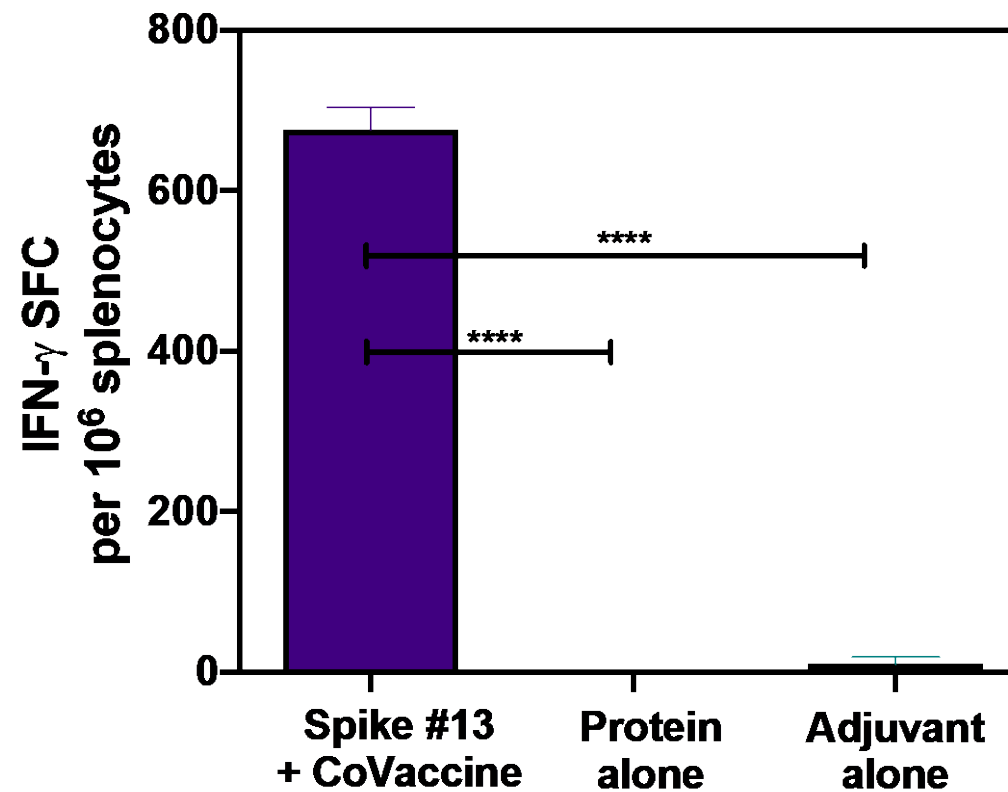
- IgG2a and IgG2b represent the Th1 response
- Study conducted in Swiss Webster mice (outbred)



# CiVax™ – Proprietary Antigen

➤ **Strong cell mediated immune response**  
after 2<sup>nd</sup> dose

- Preliminary data show high amount of cells secreting IFN- $\gamma$  representing recall memory response of splenic T-cells



# Dusquetide – Potential Therapeutic in COVID-19

- **Dusquetide (active ingredient in SGX942 for oral mucositis) has been shown to control the inflammatory response to infection while enhancing the anti-infective and tissue healing pathways**
- **Potential to provide benefit in preventing progression to and/or treating moderate to severe disease arising from SARS-CoV-2 infection:**
  - **Potentially administer to all hospitalized patients to prevent progression to severe respiratory illness**
  - **Potentially administer to moderate to severe patients to aid in the control of infection in conjunction with remdesivir**
- **Soligenix continues to seek non-dilutive funding to potentially advance the therapeutic use of dusquetide in emerging infectious diseases, including COVID-19**
  - **Funding agencies to date have been focused on re-purposing approved drugs, as opposed to evaluating drugs in clinical development**
  - **With Phase 3 outcome for dusquetide in oral mucositis rapidly approaching (Q4 2020) and with very benign safety profile observed to date, Soligenix continues to pursue multiple funding pathways**

# Daniel Ring, MBA

- **Vice President, Business Development and Strategic Planning**
  
- **22 years industry experience,**
  - **Business development experience includes work with large (e.g., Merck & Co.) and small companies**
  - **Experience with growing commercial operations (e.g., Exela Pharma Sciences LLC)**
  
- **Detailed bio at: <https://www.soligenix.com/about/executive-team/>**

# COVID-19 Vaccine Market Potential

## Potential Value

- Global COVID - 19 vaccine market is estimated to be worth approximately \$23 Billion\*
  - Current entire global vaccine market is approximately \$40B\*
- Pandemic response will require many different vaccines for worldwide coverage
- Long term value of re-vaccination of COVID-19 similar to seasonal flu vaccines
  - U.S. influenza vaccine market valued at US\$ 2.6 billion in 2019<sup>§</sup> ;
  - 2019-20 US flu season resulted in 24,000 – 62,000 flu deaths<sup>±</sup>
  - COVID-19 vaccines will likely require multiple doses over many years to achieve herd immunity

## CiVax™ Strategic Rationale

- **Size of market:** Billions of doses will be needed to satisfy global requirements providing room for multiple suppliers
- **Distribution advantage:** Employs Soligenix's thermostabilization platform ThermoVax®, which simplifies and broadens distribution by avoiding cold-chain
- **Gold standard vaccine platform:** Tried and true vaccine technology with potential lower regulatory risk and higher public acceptance
- **Seasonal use:** May be used as an annual or semi-annual booster irrespective of the vaccine utilized for the first vaccination, if the need were to arise



# First Generation Vaccines vs. Second Generation CiVax™

- **First generation vaccines utilize more novel and less understood technologies**
  - **Potential to introduce additional regulatory risk and may limit repeat use**
  - **“Tried and True” protein subunit vaccine has established regulatory and safety precedent**
    - Introduction of novel CoVaccine adjuvant expands the applicability of the standard protein vaccine approach
  - **“Tried and True” approach may address more hesitant populations**
    - Potential slow adoption of novel technologies; data show 30% of people say they will take 1st gen vaccine; 40% will wait 6-12 months and 30% >12 months
- **First generation vaccines may potentially limit availability due to both cold-chain logistical and safety constraints**
  - **CiVax may be more easily distributed (e.g., ambient temperature)**
  - **CiVax may address these other populations (e.g. elderly, immunocompromised)**
- **First generation vaccines may have limited utility for repeat vaccination**
  - **CiVax may be used to boost any other vaccine platform used for earlier immunizations**
- **First generation vaccines may identify “correlates of immune protection”**
  - **Potential to accelerate clinical development of “tried and true” vaccines with very low safety risk**

# Christopher Schaber, PhD

➤ **Chairman, President & CEO**

➤ **30 years of broad R&D and operational experience across pharmaceutical and biotech industry**

- **Discovery Laboratories (COO)**
- **Acute Therapeutics (Co-Founder)**
- **Ohmeda Pharmaceuticals**
- **The Liposome Company**
- **Wyeth Ayerst**

➤ **Detailed bio at: <https://www.soligenix.com/about/executive-team/>**

# In Summary

- Multiple products with fast track and/or orphan designation, each of which holds potential for significant commercial returns
- Phase 3 assets 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**
- Potential for significant near-term value creation
- Collaborations with biotech, academia and government agencies
- **CiVax™**: COVID-19 vaccine in development
  - Target product profile: 1 or 2 dose thermostable vaccine reconstituted water for injection immediately prior to use that elicits Th1 balanced antibody response and cell mediated response to SARS-CoV-2
- **Dusquetide**: COVID-19 therapeutic potential
  - Investigating as a potential treatment for hospitalized patients with either mild to moderate or moderate to severe COVID-19



# Question & Answer Session

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**NASDAQ: SNGX**

