ORAGENICS

Developing Vaccines & Novel Antibiotics to Treat Tomorrow's Infections

Corporate Presentation

NYSE American: **OGEN**

November 10, 2020

Safe Harbor Statement

Certain statements made in this presentation include forward-looking actions that Oragenics, Inc. ("Oragenics," or the "Company") anticipates based on certain assumptions. These statements are indicated by words such as "expect", "anticipate", "should" and similar words indicating uncertainty in facts, figures and outcomes. Such statements are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. While Oragenics believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such statements will prove to be correct. The risks associated with the Company are detailed in the Company's various reports filed by the Company with the Securities and Exchange Commission.

Oragenics Company Description

Oragenics (NYSE American: OGEN) is a development stage company dedicated to fighting infectious diseases. It is focused on advancing its TerraCoV2 vaccine candidate to combat the novel coronavirus pandemic, leveraging coronavirus spike protein research licensed from the National Institutes of Health. It is also developing lantibiotics, a novel class of antibiotic, focused on combatting multidrug-resistant organisms.

Investment Highlights

1

Recent Acquisition of Noachis Terra provides access to NIH-created SARS-CoV-2 (COVID-19) Spike Protein Vaccine Technology

Expect to enter human clinical studies in mid 2021

2

Multi-billion market for COVID-19 vaccines likely to accommodate multiple players

Cash through early 2021

3

Lantibiotics Platform: A novel class of peptide antibacterial compounds, with activity against a variety of MDR infections

Lead lantibiotic OG716 addresses *C. difficile*

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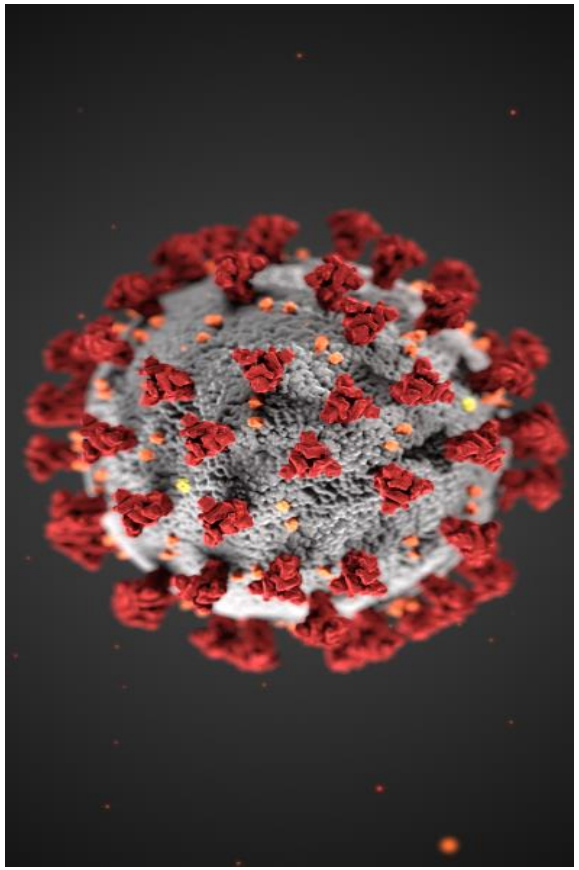
Lead Program:
NIH-created SARS-CoV2 S-2P (COVID 19) vaccine candidate focused on the stabilized "Spike Protein"

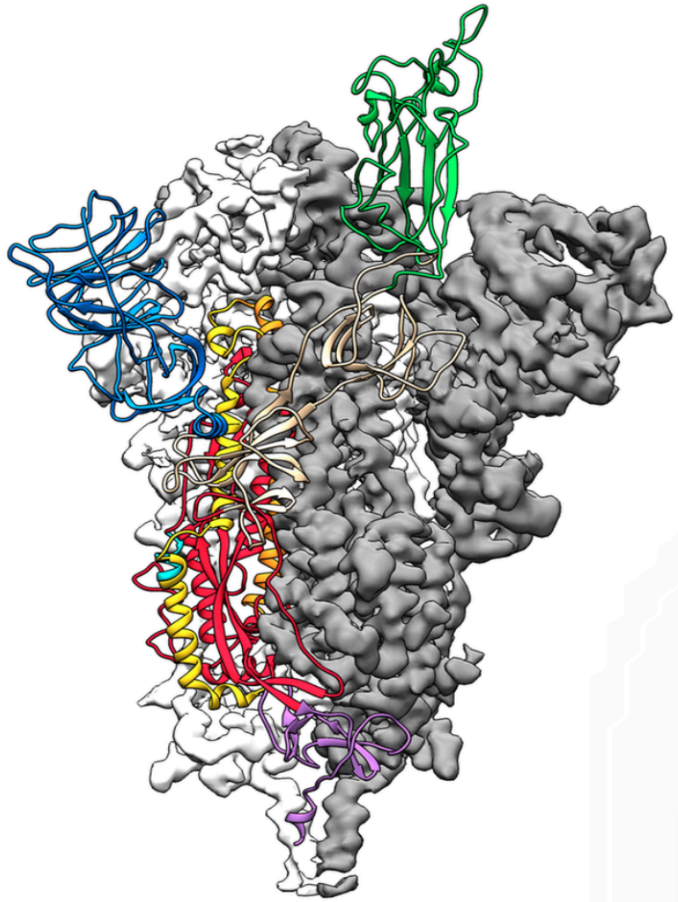
Overview



Objective: To develop and commercialize a vaccine providing long lasting immunity from SARS-CoV-2 infection focusing on the spike protein.

Benefits: Long lasting protection from SARS-CoV-2 virus, COVID-19 infection prevention, more rapid immune response, lower antigen concentration required.

Future: Potential cross protection against other coronaviruses.



The molecular structure of the spike protein.

Jason McLellan/Univ. of Texas at Austin

Corona Viruses Technology Overview – RSV F Protein: Spike Proteins Continually Changing Shape

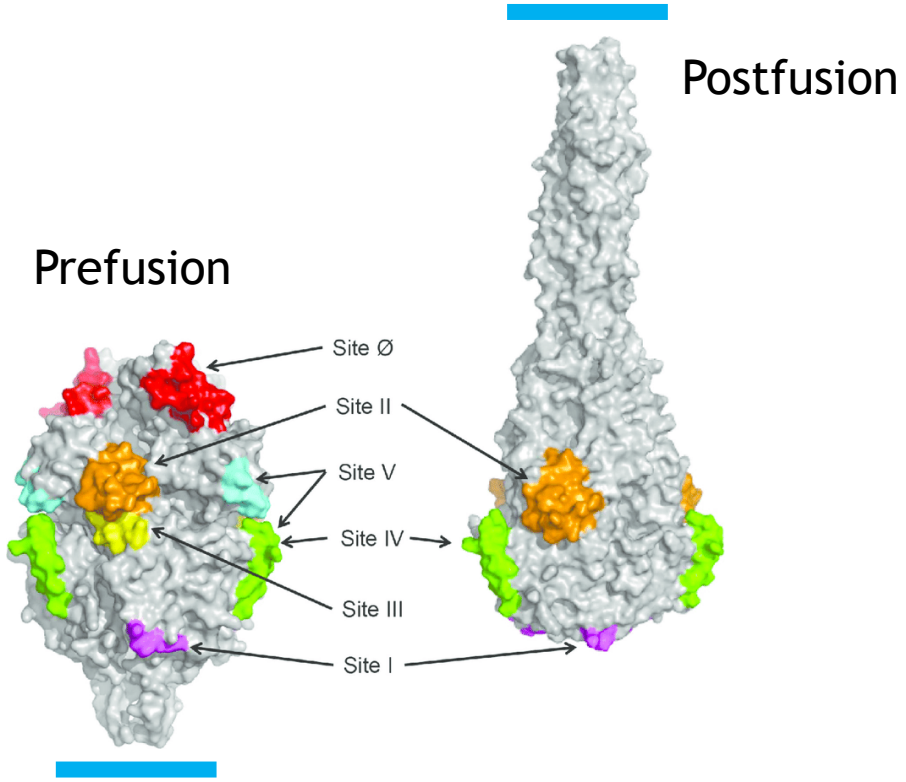
Accessible antigenic sites depend on protein conformation:

- **Pre sites: Ø, V**
- **Post site[1]: I**
- **Pre/post sites: II, III, IV**

Absorption of human convalescent serum with postfusion F modestly reduces neutralizing antibodies

Absorption of human convalescent serum with prefusion F removes almost all neutralizing antibodies

1. MAbs to site 1 preferentially bind postfusion conformation

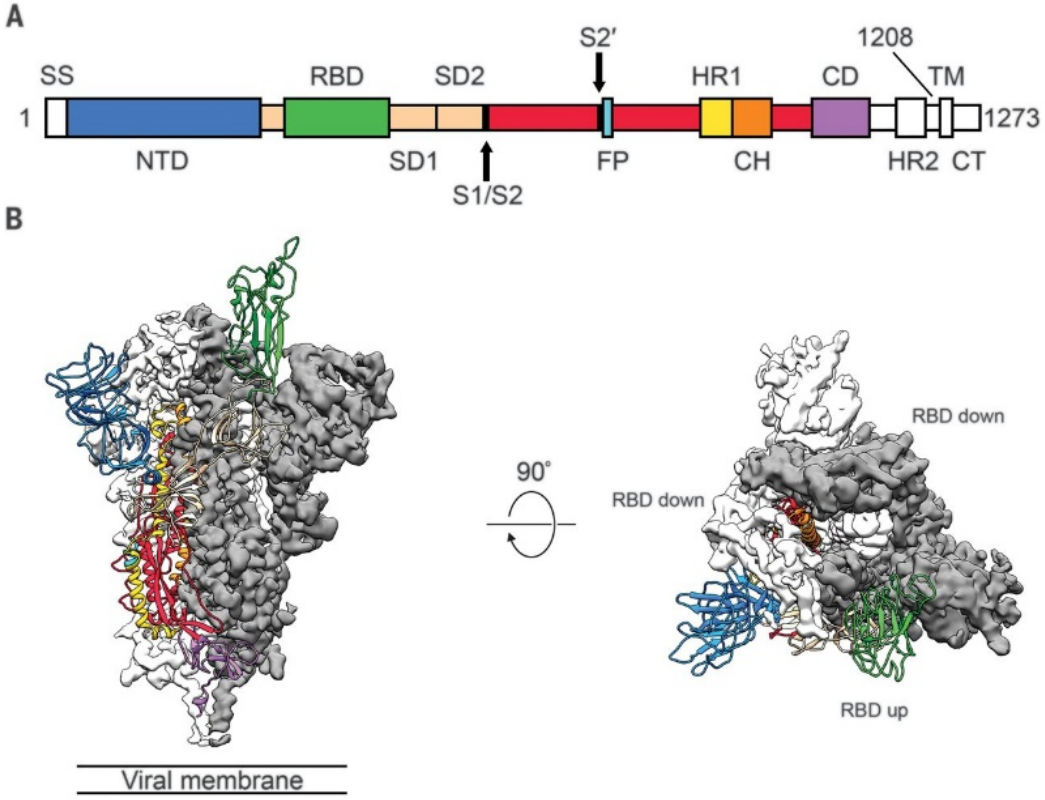


Flynn et al, PLOS ONE|DOI:10.1371/journal.prone.0164789 Oct. 20, 2016

Corona Virus Technology Overview – Enhanced Immune Response Utilizing Stabilized Spike Protein Antigen

Stabilized Prefusion Spike Protein Ectodomain Trimer

- Class I fusion protein
- Two amino acid substitutions stabilize prefusion conformation
- T4 fibritin trimerization domain
- Expressed in mammalian cell line; Chinese Hamster Ovary (CHO) cells



Daniel Wrapp et al. Science 2020; 367:1260-1263

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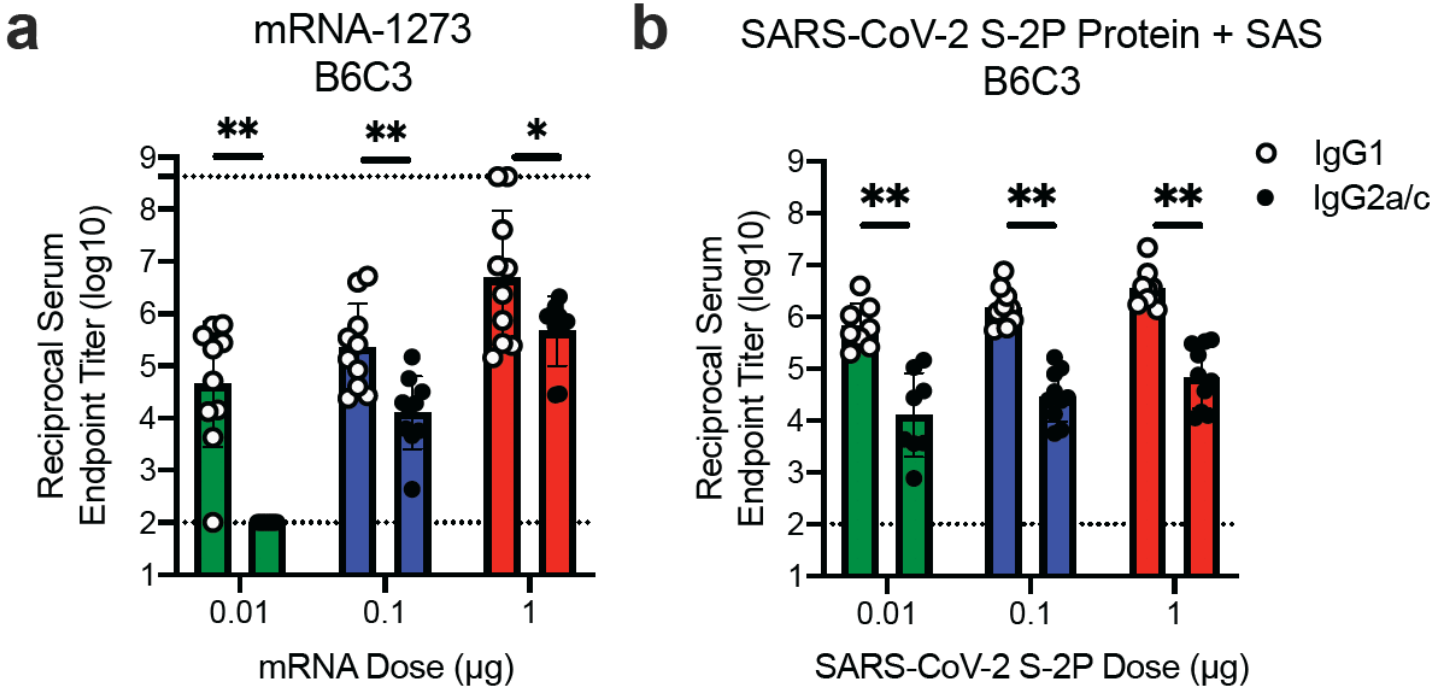
SARS-CoV-2 S-2P IgG subclass Results: B6C3 Mice



Immunizations with mRNA-1273 and S-2P protein, delivered with TLR4 agonist, elicit S-specific Th1-biased T cell responses. **B6C3F1/J mice were immunized at weeks 0 and 3 with 0.01, 0.1, or 1 *µ*g of mRNA-1273 or SAS-adjuvanted SARS-CoV-2 S-2P protein.** Sera were collected 2 weeks post-boost and assessed by ELISA for SARS-CoV-2 S-specific IgG1 and IgG2a/c.

Endpoint titers (a-b) were calculated. For mice for which endpoint titers did not reach the lower limit of detection (dotted line), ratios were not calculated (N/A).

SARS-CoV-2 S-2P protein with SAS adjuvant produces significant and balanced IgG1 and $IgG2_{a/c}$ levels at doses as low as 0.01 ug demonstrating level of immune response.

Corbett *et al*, BioRxiv. 2020. https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1

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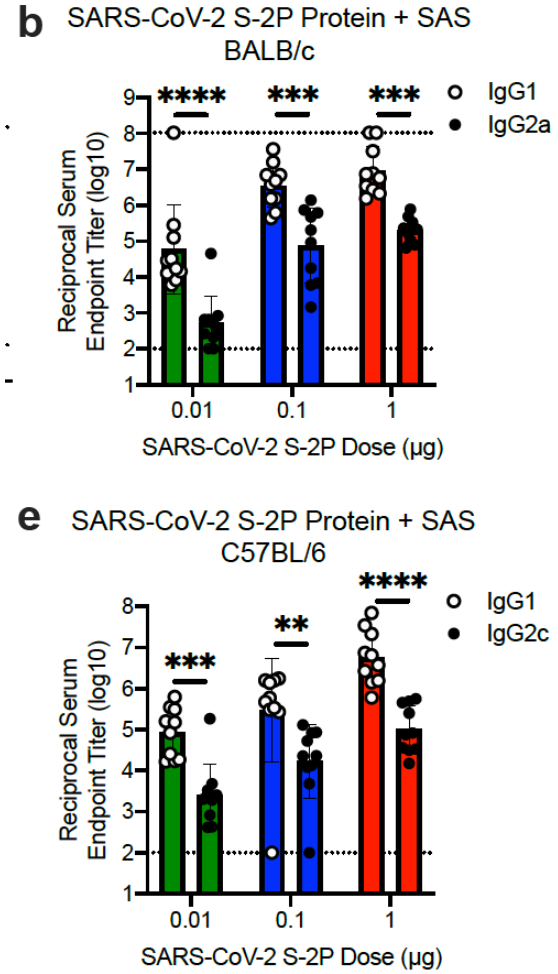
SARS-CoV-2 S-2P IgG subclass Results: BALB/c and C57BL/6 Mice



SAS-adjuvanted S-2P protein elicit both IgG2a and IgG1 subclass S-binding antibodies. BALB/cJ (b) or C57BL/6J (e) mice were immunized at weeks 0 and 3 with 0.01 (green), 0.1 (blue), or 1 µg (red) of SARSCoV- 2 S-2P protein adjuvanted with SAS. Sera were collected 2 weeks post-boost and assessed by ELISA for SARS-CoV-2 S-specific IgG1 and IgG2a or IgG2c for BALB/cJ and C57BL/6J mice, respectively.

Similar significant and balanced IgG1 and $IgG2_a$ or $IgG2_c$ titers were also observed in BALB/c and C57BL/6 mice immunized with SARS-CoV-2 S-2P protein with SAS adjuvant indicating the immune response is robust and seen in a second strain of mouse.

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SARS-CoV-2 S-2P Neutralization Titers

Extended Data Table 1. Concordance of Pseudovirus Neutralization Assay and PRNT.

Mouse Serum Pool #[1]	Reciprocal IC_{50} Titer		*Fold Difference*[4]
	Pseudovirus Neutralization[2]	PRNT[3]	
1	893.5 +/- 1.4	933.5	*1.0*
2	211.6 +/- 1.5	314.5	*0.7*
3	159.8 +/- 1.3	397.1	*0.5*

1. BALB/cJ mice were immunized at weeks 0 and 3 with 1 µg SARS-CoV-2 S-2P protein, adjuvanted with SAS. Sera were collected 2 weeks post-boost and pooled (N = 3 mice/pool).
2. IC50 titers were averaged from pseudovirus neutralization assays completed in 5 experimental replicates. (GMT +/- geometric SD)
3. IC50 titer from PRNT assay completed once.
4. Fold difference calculated as average pseudovirus neutralization IC50 titer relative to PRNT IC50
Titer

SARS-CoV-2 S-2P protein with SAS adjuvant produces significant Nab titers in BALB/c mice.

Well Established Production Process for Terra Cov-2 Vaccine Creation

Creation of Antigen Producing cell line (CHO) (Aragen)

Production of Antigen under GMP (Avid)

Addition of FDA approved Adjuvant

Completion of Fill/Finish (Catalent)

Examples of recombinant protein + Adjuvant
Hepatitis B
HPV

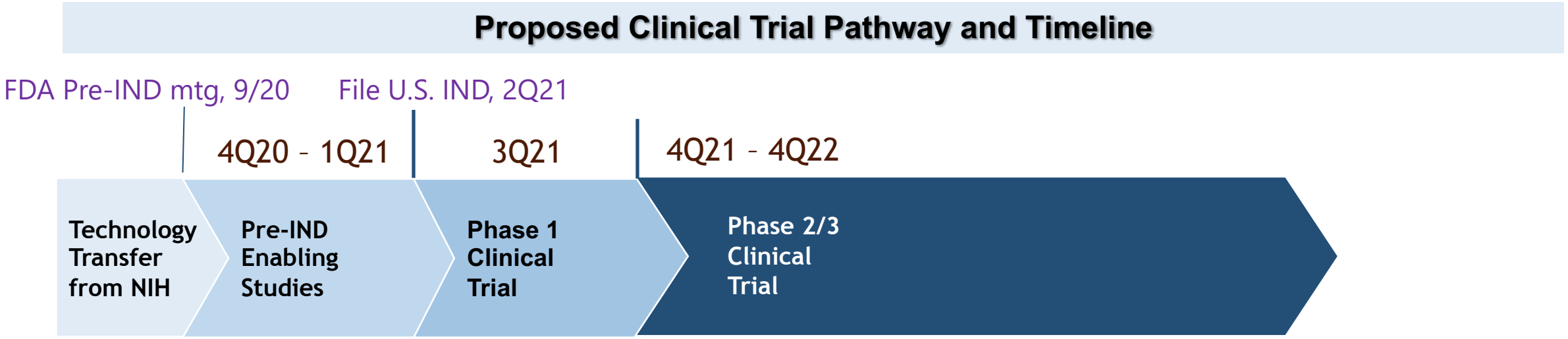
Key Vaccine Attributes

- Well established vaccine product characteristics: recombinant protein + adjuvant (Hep B, HPV, Influenza vaccines)
- Potential for single dose efficacy (based on Phase 1 results)
- Provided in pre-filled syringes – ease of use……
- Storage and transport at refrigerated (5ºC) temperatures: not -50º to -80ºC
- Advantage for remote locations, particularly in 2nd and 3rd tier countries
- Designed for availability and use post-pandemic distribution

Technology Overview – Current Status

- NIH/NIAID license secured with acquisition of Noachis Terra
- Non-dilutive grants, primarily DoD, under development
- Contracts in place for:
  - Cell bank manufacture
  - Vaccine manufacture
  - Clinical Research Organization & Regulatory Consultants
- **Creation of cell line complete**
- **Development of analytical methods and transfer to manufacturing facility underway**
- **FDA pre-IND meeting complete**

Regulatory Strategy: Aggressive Fast Track Approach



Assumptions:

1. RCB used as GMP cell line
2. Pilot batch acceptable for IND and Phase 1
3. Toxicology study report initially filed with clinical only

Why Invest Now? Vaccine News Flow

- 1Q21:
  - Release of NIH confidential viral load data
  - Completion of mouse immunogenicity study
  - Completion of hamster challenge study
  - Announcement of adjuvant access deal
- 2Q21:
  - Complete creation of Master Cell Bank for GMP production
  - File IND and initiate Phase 1clincal study activities
- 3Q21
  - Non-dilutive funding or partnership?

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Novel Lantibiotic Platform for Multidrug Resistant Bacterial Infections

2019 CDC List of Antibiotic Resistant Bacteria and Fungi

Urgent Threats

- Carbapenem-resistant *Acinetobacter*
- *Candida auris*
- *Clostridioides difficile*
- Carbapenem-resistant Enterobacteriaceae
- Drug-resistant *Neisseria gonorrhoeae*

Serious Threats

- Drug-resistant *Campylobacter*
- Drug-resistant *Candida*
- ESBL-producing Enterobacteriaceae
- Vancomycin-resistant *Enterococci* (VRE)
- Multidrug-resistant *Pseudomonas aeruginosa*
- Drug-resistant nontyphoidal *Salmonella*
- Drug-resistant *Salmonella* serotype Typhi
- Drug-resistant *Shigella*
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Drug-resistant *Streptococcus pneumoniae*
- Drug-resistant Tuberculosis

Concerning Threats

- Erythromycin-Resistant Group A *Streptococcus*
- Clindamycin-resistant Group B *Streptococcus*

Watch List

- Azole-resistant *Aspergillus fumigatus*
- Drug-resistant *Mycoplasma genitalium*
- Drug-resistant *Bordetella pertussis*

Lantibiotics: Novel Platform of Antibiotics to Treat Serious Life-Threatening Infections

- Lantibiotics are a novel class of peptide antibacterial compounds naturally produced by a variety of Gram-positive bacterial strains to attack competing bacterial strains
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Platform provides potential for development in multidrug resistant infections:
  - Methicillin Resistant *Staphlococcus aureus* (MRSA)
  - Vancomycin Resistant Enterococci (VRE)
  - Virulent *Clostridium difficile*
  - Gram(-) infections

Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

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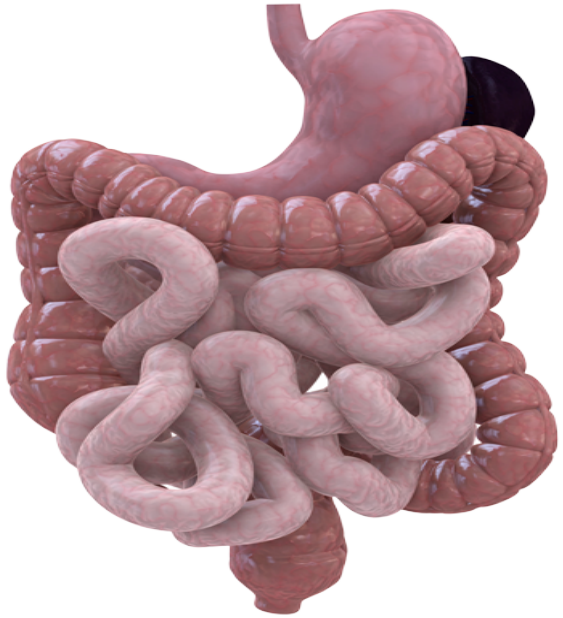
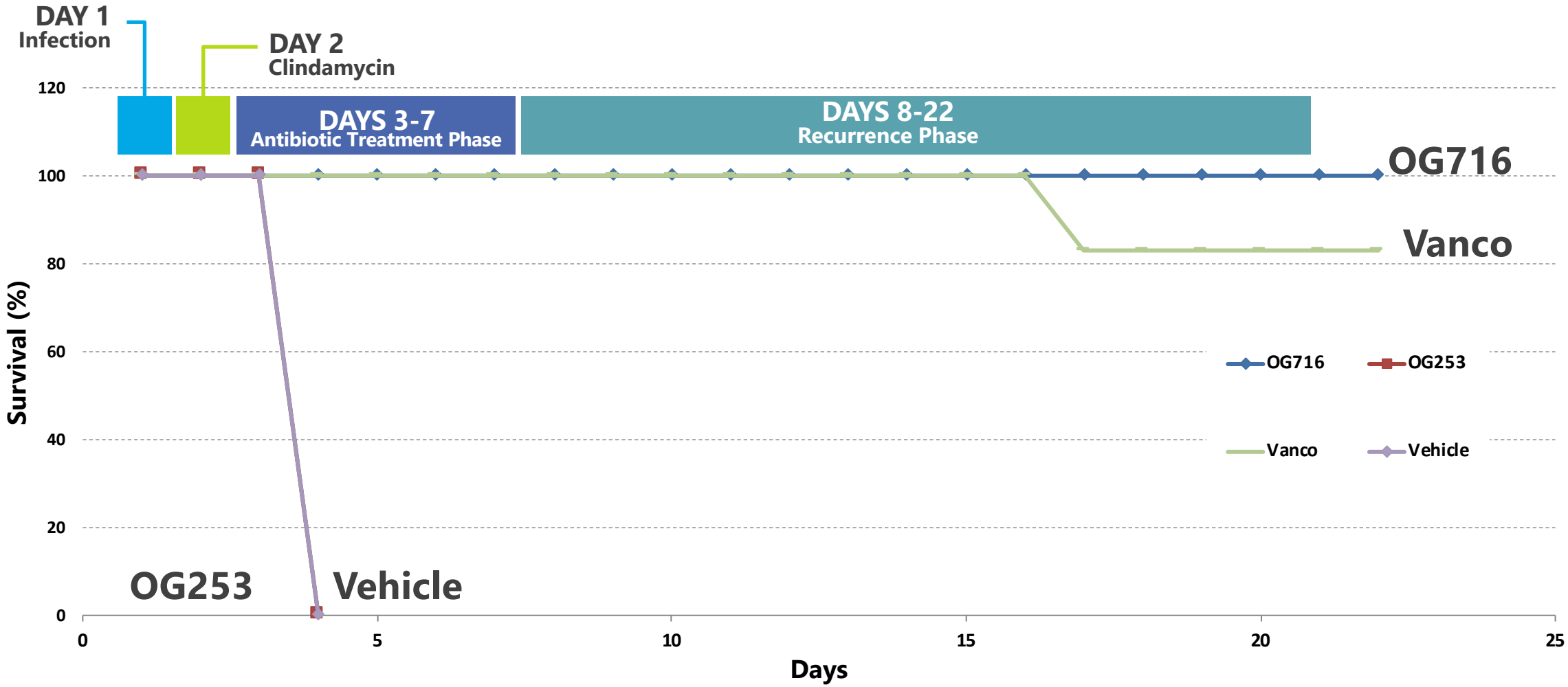
C. difficile and *C. difficile* Infection (CDI): Epidemiology



- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage lining of the colon
- 223,900 infections annually resulting in 12,800 deaths
- 83,000 will experience at least one recurrence
- Healthcare-associated infections occur: 37% hospital onset, 36% nursing home onset, and 27% community onset
- *C. difficile* associated diarrhea is associated with a 1-2 week hospital stay at a cost of $1BN/year
- **Emerging problem**: 8% of CDI associated with onset of concomitant Vancomycin Resistant Enterococci (VRE) infection

Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



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Lantibiotics: OG716 *C. difficile* Program Milestones

4Q16

Tech Transfer of Manufacturing Process

Fermentation complete; purification underway

1Q17

Manufacture of API

Ongoing at 1400L scale: transitioning to GMP manufacture; Enough material generated for rat tox study, lots for monkey tox study ongoing

3Q19

Toxicology and Microbiology Underway

14-day rat tox study underway and monkey tox study under development

2Q21 (estimate)

File IND

Timing of filing of the IND is subject to having adequate available capital to complete requisite studies

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Corporate Status Update

Capitalization

	Common Stock Equivalents
Common Stock Outstanding[(1)]	61,004,917
Series A and Series B Convertible Preferred (As Converted)	2,261,703
Series C Non-Convertible Perpetual Preferred[(2)] (113.941 shares outstanding)	-
Warrants (WAEP $1.36) [(1)]	20,513,145
Reserved for issuance under stock incentive plan	8,009,250
Total	91,789,015

Cash	$10.0M[(3)]

(1) Information is as of September 30, 2020.

(2) As of September 30, 2020, the Non-Voting, Non-Convertible Series C Preferred Shares have a stated value of $33,847 per share and have an accruing dividend of 20% per year. The Series C Preferred Shares resulted from the conversion of approximately $3.3 million in debt obligations previously owed to Precigen (fka: Intrexon).

The Series A, B, and C Preferred stock have no price based downround protection for the conversion price.

(3) Information is as of September 30, 2020.

Near Term Milestones

3Q20

- Complete CHO cell line Vaccine Development
- Initiate Vaccine CDMO work
- Complete FDA pre-IND meeting for Vaccine Candidate

4Q20

- Initiate pre-clinical studies for Vaccine Candidate
- Advance Vaccine GMP manufacture at CDMO
- Initiate building of CHO MCB for the Vaccine

2Q21

- File IND for Vaccine
- Initiate Phase 1 Clinical Study

2Q21

- File IND for OG716

Investment Summary

- License to NIH-created SARS-CoV-2 Spike Protein Vaccine Technology set to enter human clinical studies in early 2021; potential for long lasting protection for SARS-CoV-2 and other coronaviruses

- $Multi-billion market for COVID-19 vaccines likely to accommodate multiple players

- Cash through early 2021; Federal Grants for COVID-19 under review

- Novel class of peptide antibacterial compounds called Lantibiotics
  - Activity against a variety of MDR infections, believed to be the next human health crisis
  - Lead lantibiotic OG716 addresses *C. difficile* – a significant infection identified by the CDC.

Experienced Management Team

Dr. Alan F. Joslyn
Director, President and Chief Executive Officer

- Assumed CEO position at Oragenics in June 2016
- Held CEO positions at several private biotechnology companies including Sentinella Pharmaceuticals, Edusa Pharmaceuticals and Mt. Cook Pharma
- Over 25 years of drug development experience at Glaxo, Johnson & Johnson and Penwest

Mike Sullivan
Chief Financial Officer

- Held senior-level financial positions for both publicly and privately held businesses
- Significant experience in product licensing and IP issues with strong background in both domestic and international retail operations

Dr. Martin Handfield
Senior Vice President, Discovery Research

- Molecular Microbiologist and former Tenured Associate Professor, College of Dentistry at The University of Florida
- Prolific researcher focusing on infectious diseases, host-pathogen interactions and non-invasive diagnostics

Experienced Management Team

Dr. David Zarley
Consultant

- More than 30 years in vaccine research and development in the private sector
- Vice-President of Program Management for Vaccine Research and Development at Pfizer
- Senior Director /Medicines Team Leader for Pfizer Primary Care Business Unit
- Senior Director for Wyeth Research Project Management Business Unit
- Senior Director for Technical Operations and Product Supply (TOPS) at Wyeth Vaccines
- Senior Research Biochemist / Project Leader for Viral Vaccine Research and Development at Lederle-Praxis Biologicals

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