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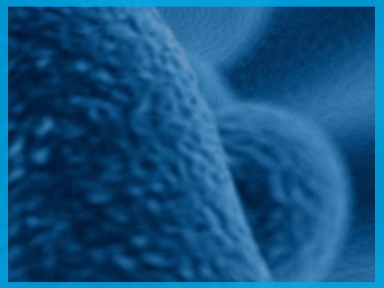

DEVELOPING NOVEL ANTIBIOTICS AND BIOTHERAPEUTICS THROUGH SYNTHETIC BIOLOGY

Investor Presentation

NYSE American: OGEN

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.

Investment Highlights

1

Phase 2 ongoing clinical program in a ~$25MM market cap company with near-term catalysts; recent positive interim safety results

2

AG013 for Oral Mucositis: Large unmet clinical need - no drug is approved to prevent OM in the broad cancer population; Affects >770,000 cancer patients annually in the US

3

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

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AG013: First-in-Class Therapy for Oral Mucositis

Oral Mucositis

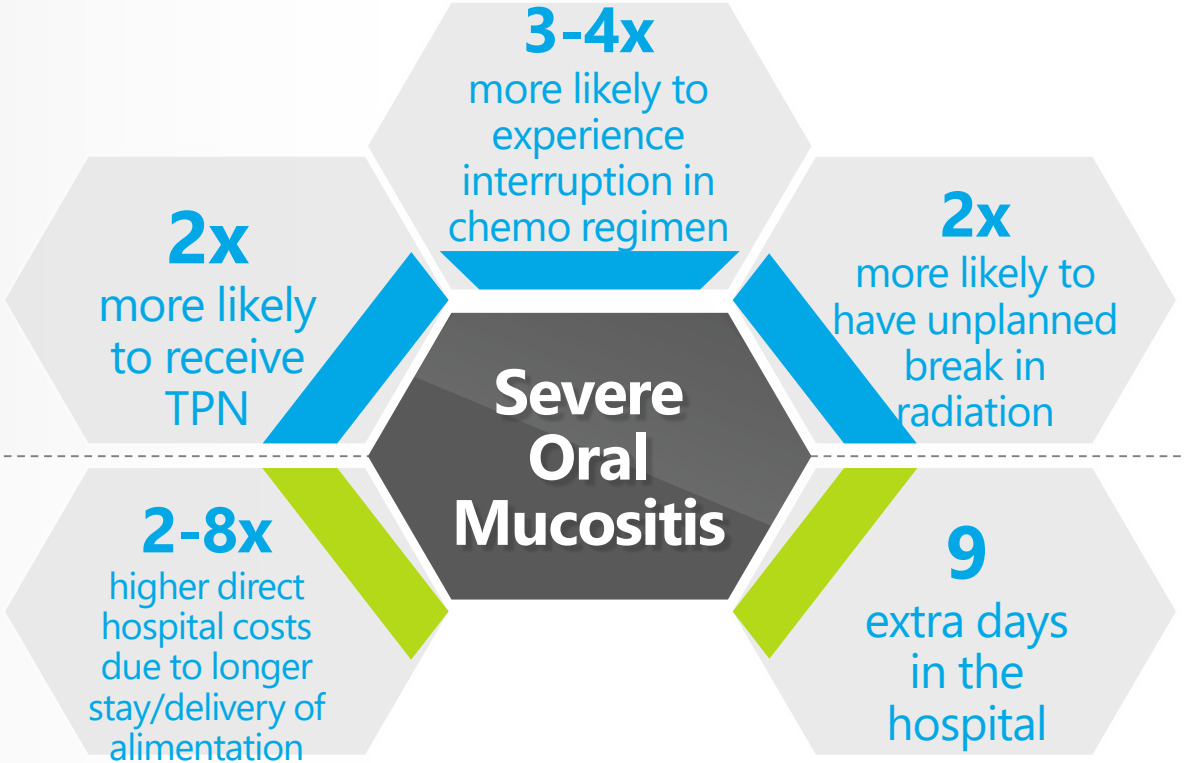
- Most common and debilitating complication of cancer chemo and radiation therapy.
- Caused by breakdown of mucosal lining resulting in formation of oral ulcers.
- Inability to eat/drink (WHO grades 3 & 4) resulting in nutritional deficits and potential alterations of cancer treatment regimens.
- **Large Addressable Market**: > 770,000 U.S. newly diagnosed cancer patients receiving conventional chemotherapy and radiation are at increased risk of developing OM*

*Center Disease Control, 2017

Economic and Clinical Impact of Severe OM

Clinical Impact:

Economic Impact:



Nonzee et al Cancer 2008; 113: 1446-52
Vera_Llonch et al Cancer 2006: 106: 329-36
Carlotto et al Pharmacoeconomics 2013: 2013: 753-66

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AG013: Target Product Profile

- Convenient, flavored oral rinsing solution composed of genetically modified *Lactococcus lactis* (non-pathologic food grade bacterium) engineered to deliver mucosal protectant human Trefoil Factor 1 (hTFF1) to mucosal tissues
  - Trefoil Factors (TFF's) are a class of peptides involved in protecting mucosal tissues against damage and in subsequent repair
- Cost effective (low COGs) rinse provides daily continuous oropharyngeal coverage with *L. lactis* producing hTFF1 during entire cancer treatment regimen

Efficacy endpoints include:

Prevention: No severe OM (WHO grade 3 or 4) during chemoradiation course

Treatment: Reduced number of days of severe OM versus comparator (standard of care)

AG013 in Action

1

AG013 is delivered via lactococcus

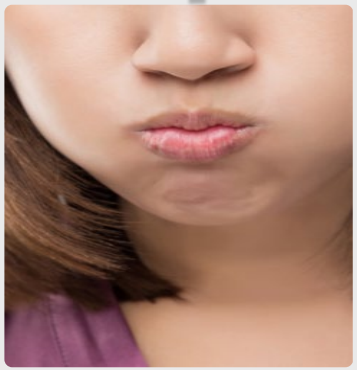
2

The combination is freeze-dried into vials

3

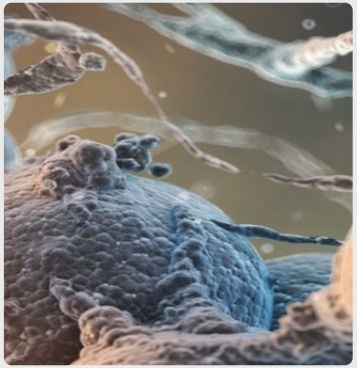
Patient mixes powder with a raspberry-flavored solution

4



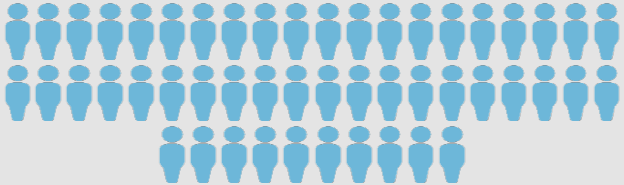
Patient swishes for 30 seconds after every meal

5



This activity promotes a protein called trefoil factor, which regrows the oral lining

AG013 Superior to Available Treatments

	AG013	Kepivance
Sales	TBD	$14,000,000
Patients	 >500,000	20,000 (indicated only for bone marrow transplant induction chemo patients)
Method	Oral rinse, outpatient	Intravenous, inpatient

$600MM palliative care products provide temporary symptomatic relief

* All figures approximate;

AG013 Has Large Addressable Market With Potential W.W. Sales >$1.0Bn for Oral Mucositis

REVENUE-BASED FORECAST ASSUMPTIONS

Potential Global Market:

6.2 MILLION+
new patients ww/yr

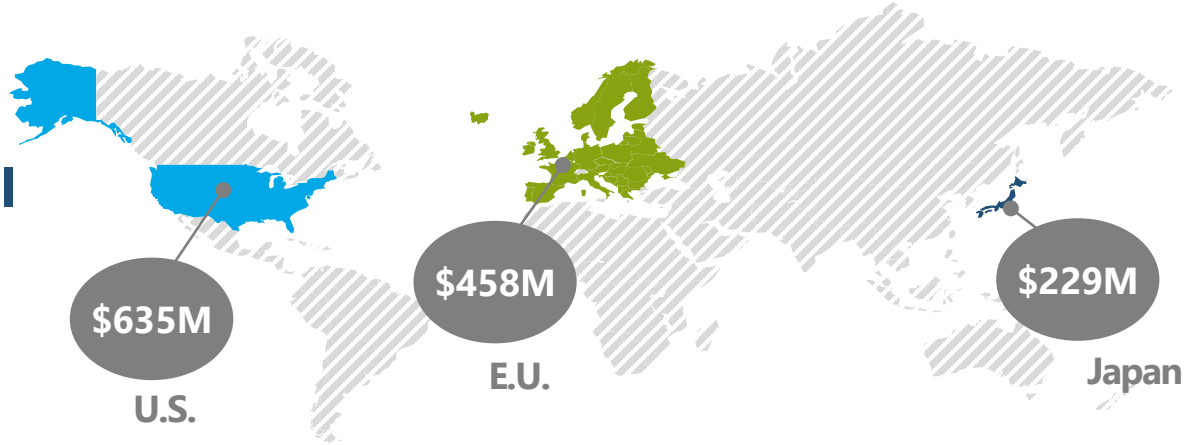
Peak Share:

20-25%

Cost:

$100
per day

Global Peak Sales:



Gross Margin:
90%

Intellectual property relating to AG013 extends into 2030s

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AG013: Phase 2 Study Design Agreed with FDA

- Double-blind, placebo – controlled evaluation of daily AG013 ($2x10^{11}$ CFU) TID oral rinse for duration of cancer treatment regimen
- 160-180 evaluable patients with head and neck cancer receiving chemoradiation therapy over 7-9 weeks and standard of care for prevention of OM
- ~57 clinical centers in United States and Europe
- **Primary efficacy endpoint:** Duration (in days) of severe OM (WHO grades 3 (unable to eat) & 4 (unable to drink))
- **Sample size consideration:** 160 evaluable patients (80/group) provides 80% power to detect 5-day difference between groups with respect to severe OM
- **OM secondary endpoints:** number of OM free (WHO grades 1 & 2) days, time to onset, use of pain medication, alteration in cancer regimens

AG013 Received **FDA Fast Track** Designation

AG013 Clears FDA Safety Hurdle: Positive Interim Safety Results

- 24 Patients randomized with 19 patients completing therapy.
- Adverse event profiles similar between AG013 and Placebo.
- Serious Adverse Events consistent with Head and Neck Cancer Patients: fever, neutropenia, infections, nausea & vomiting.
- No reports of bacteremia or sepsis
- Discontinuations:
  - **Severe Oral Mucositis: 3 patients**
  - **Nausea & Vomiting: 3 patients**
  - **Non-compliance: 2 patients**

AG013: Timeline of Key Events

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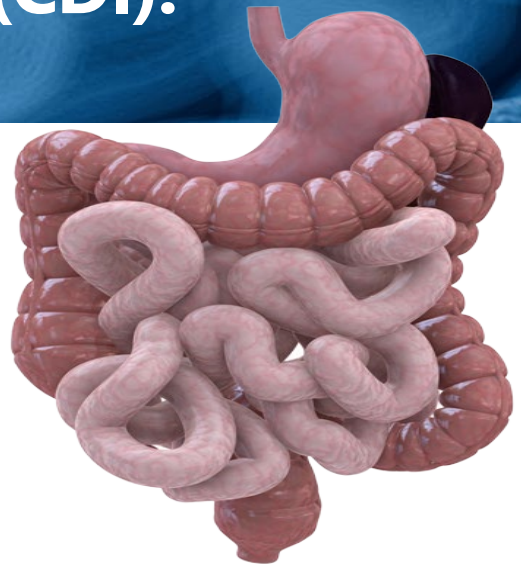
Novel Lantibiotic Platform for Multidrug Resistant Bacterial Infections

CDC Antibiotic-Resistant Threats, 2017 (cases/yr, US)

Drug-resistant pathogen	blue = gram (+) grey= gram (-)	Infections/year
Clostridium difficile		**500,000**
Carbapenem-Resistant Enterobacteriaceae (CRE)		9,000
Neisseria gonorrhoeae		246,000
MDR Acinetobacter		7,300
Drug-Resistant Campylobacter		310,000
Extended Spectrum ß-lactamase Enterobacteriaceae		26,000
Vancomycin-Resistant Enterococcus (VRE)		**20,000**
MDR *Pseudomonas aeruginosa*		6,700
Drug-Resistant Non-Typhoid Salmonella		100,000
Drug-Resistant Typhoid Salmonella		3,800
Drug-Resistant Shigella		27,000
Methicillin-Resistant *Staphylococcus aureus* (MRSA)		**80,000**
Drug-Resistant *Streptococcus pneumoniae*		**1,200,000**

Center Disease Control; U.S. MDR pathogen update, 2017

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
- 500,000 infections annually resulting in 29,000 deaths
- 83,000 will experience at least one recurrence
- Deaths have increased 400% since 2000
- Healthcare-associated infections occur: 37% hospital onset, 36% nursing home onset, 27% community onset
- *C. difficile* associated diarrhea is associated with a 1-2 week hospital stay
- **Emerging problem**: 8% of CDI associated with onset of concomitant Vancomycin Resistant Enterococci (VRE) infection

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

- Lantibiotics are novel class of peptide antibacterial compounds naturally produced by variety of Gram-positive bacterial strains to attack competing bacterial strains
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Prior development limited by manufacturing technical hurdles
- 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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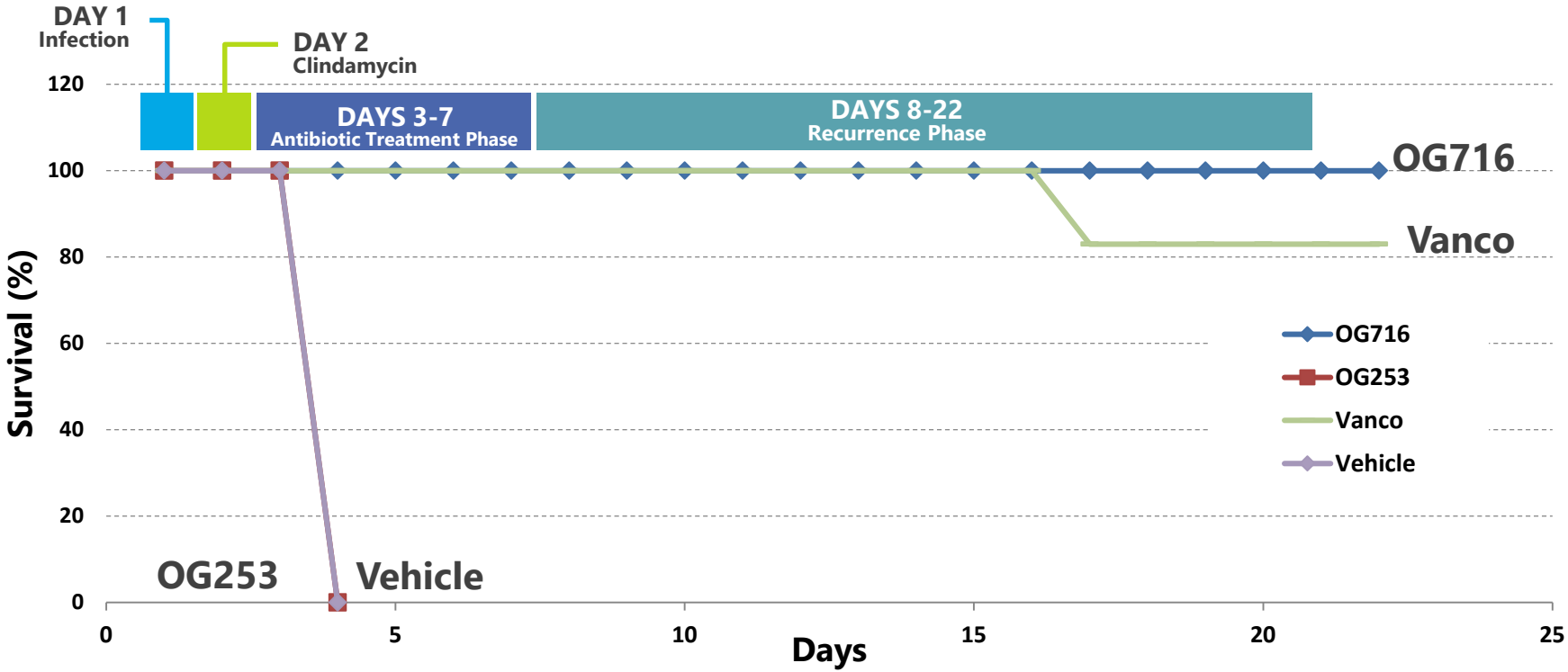
Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



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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

4Q18

Toxicology and Microbiology Underway

Single dose-escalating rat study complete and results discussed with FDA; rat and monkey 14-day tox studies under development

2Q20 (estimate)

File IND

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

Corporate Status Update

Capitalization

	Common Stock Equivalents
Common Stock Outstanding *	46,112,303
Series A Convertible Preferred*	941,701
Series B Convertible Preferred*	1,320,002
Series C Non-Convertible Perpetual Preferred*** (113.941 shares outstanding)	-
Warrants*	26,538,593
Reserved for issuance under stock incentive plan*	2,009,250
Total	76,921,849

Major Shareholders	Common Stock	Common Stock Equivalents
Koski Family	4.05%	3.35%
Intrexon Corporation (NYSE:XON)	3.36%	2.01%

Pro-Forma Cash**	$29.8M

* Information is as of March 25, 2019.

** Information is as of March 25, 2018 and includes proceeds of ~$11.5 million from March 2019 financing.

*** As of November 8, 2017, the Non-Voting, Non-Convertible Series C Preferred Shares have a stated value of $33,847 per share and have an accruing dividend of 12% per year. The Series C Preferred Shares resulted from the conversion of approximately $3.3 million in debt obligations previously owed to Intrexon.

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

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
- Presently sits on the board of Synergy Pharmaceuticals (NASDAQ: SGYP)
- 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