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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934.**

**Date of Report: September 27, 2018 (Date of earliest event reported)**

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**Oragenics, Inc.**

(Exact name of registrant as specified in its charter)

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**FL**  
(State or other jurisdiction  
of incorporation)

**001-32188**  
(Commission  
File Number)

**59-3410522**  
(IRS Employer  
Identification Number)

**4902 Eisenhower Boulevard, Suite 125**  
**Tampa, FL**  
(Address of principal executive offices)

**33634**  
(Zip Code)

**813-286-7900**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former Name or Former Address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 5.02. DEPARTURE OF DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.**

*(e) Compensatory Arrangements of Certain Officers.*

*Executive Officer Equity Awards.* On September 27, 2018, the Board of Directors of the Orogenics, Inc. (“Orogenics” or the “Company”) approved discretionary stock option awards, as recommended and approved by the Compensation Committee, for the Company’s executive officers and certain currently employees. Dr. Alan Joslyn, the Company’s Chief Executive Officer, Mr. Michael Sullivan, the Company’s Chief Financial Officer, and Dr. Handfield, the Company’s Senior Vice President of Discovery Research, were granted options to purchase 400,000, 250,000 and 220,000 shares of Company common stock, respectively, under the Company’s 2012 Equity Incentive Plan, as amended (the “Plan”) at an exercise price of \$0.73 per share, the closing price on September 27, 2018, the date of grant. A third of the options are vested immediately and two third of the options are subject to time-based vesting, with a third vesting on each of the first and second anniversaries of the date of the grant, subject to the recipient remaining employed with the Company through the vesting dates. The stock option awards are subject to the standard terms and conditions of the Company’s form of stock option agreement which includes earlier vesting upon a change in control of the Company.

**Item 8.01 Other Events.**

*Non-Employee Director Equity Awards.* On September 27, 2018, the Board of Directors approved discretionary stock option awards providing the right to acquire 125,000 shares of common stock, to each of the Company’s non-employee directors: Frederick Telling, Charles Pope, Alan Dunton, and Robert Koski under the Plan at an exercise price of \$0.73 per share, the closing price on September 27, 2018, the date of grant. The options vest immediately. The stock option awards are subject to the standard terms and conditions of the Company’s form of stock option agreement.

*Investor Presentation.* On October 1, 2018 the Company posted on its website a copy of an updated investor presentation (the “Investor Presentation”) a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company also expects to use the Investor Presentation from time to time in connection with presentations to potential investors, industry analysts and others. The Investor Presentation is available under the “Presentations” tab in the “News and Media” section of the Company’s website, located at [www.orogenics.com](http://www.orogenics.com). The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company’s Securities and Exchange Commission (“SEC”) filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

*Common Stock Outstanding.* Due to the voluntary conversions by certain holders of Series D Convertible Preferred stock (“Series D Preferred Stock”) the Company’s outstanding shares of Series D Preferred Stock have decreased and the Company’s outstanding shares of common stock have increased. As of September 30, 2018, the Company had 1,496,000 shares of Series D Preferred Stock and 18,419,135 shares of common stock outstanding.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Investor Presentation</u></a>

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**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 1<sup>st</sup> day of October, 2018.

**ORAGENICS, INC.**  
**(Registrant)**

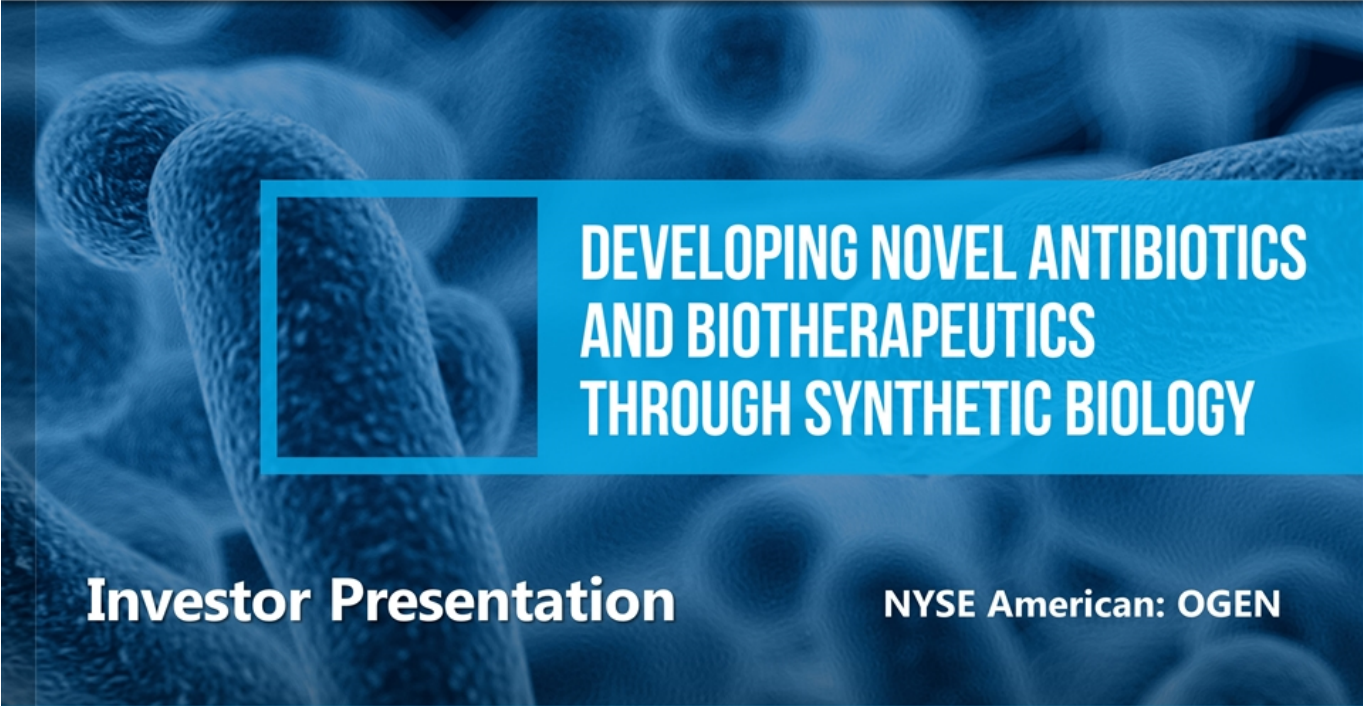
BY: /s/ Michael Sullivan  
Michael Sullivan  
Chief Financial Officer



**Exhibit 99.1**

**Alan F. Joslyn, PhD**  
President & CEO  
813 286 7900 ext 232  
ajoslyn@oragenics.com

Oragenics, Inc.  
4902 Eisenhower Blvd., Suite 125  
Tampa, FL 33634  
www.oragenics.com

A blue-tinted microscopic image of various bacteria, including some with long, hair-like appendages (flagella). A blue rectangular box highlights a portion of the image on the left side of the main title.

## **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

2

3

Phase 2 ongoing clinical program in a ~\$13MM market cap company with near-term catalysts; recent positive interim safety results

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



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

A microscopic image showing several elongated, textured cells, likely oral mucosal cells, in shades of blue. The cells are arranged in a somewhat parallel fashion, with some in the foreground and others blurred in the background.

**AG013: First-in-Class Therapy for  
Oral Mucositis**



## Oral Mucositis

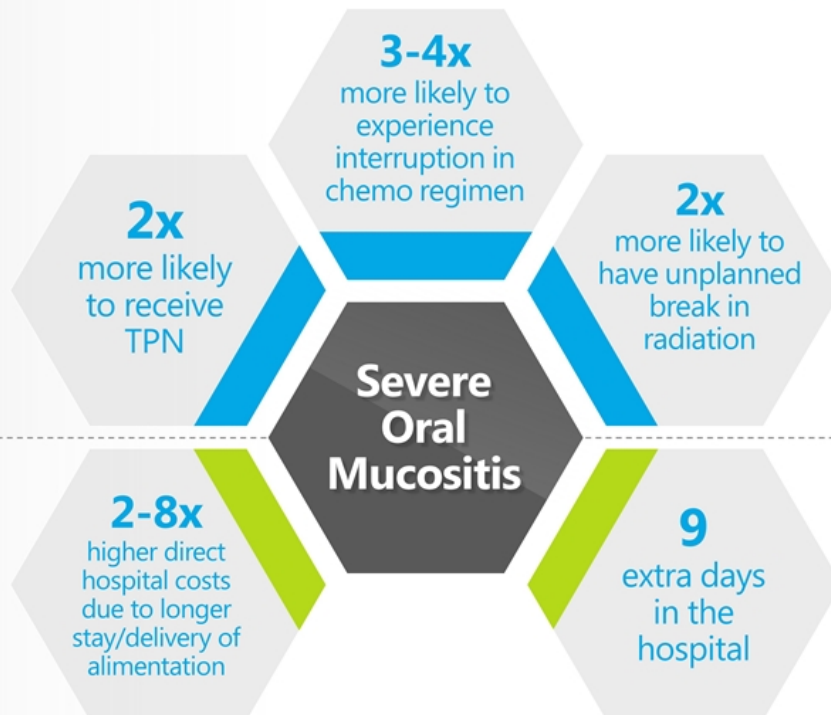


- Most common and debilitating complication of cancer chemo and radiation therapy.
- Caused by breakdown of mucosal lining resulting in formation of oral ulcers.
- Inability to eat/drink (WHO grades 3 & 4) resulting in nutritional deficits and potential alterations of cancer treatment regimens.
- **Large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



# 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

## 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

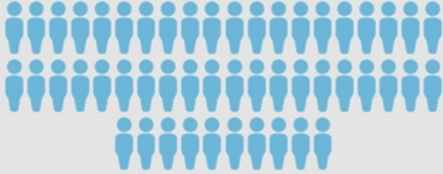





This activity promotes a protein called trefoil factor, which regrows the oral lining

# AG013 Superior to Available Treatments

## AG013

## Kepivance

Sales	TBD	\$14,000,000
Patients	 <p>&gt;500,000</p>	 <p>20,000 (indicated only for bone marrow transplant induction chemo patients)</p>
Method	 <p>Oral rinse, outpatient</p>	 <p>Intravenous, inpatient</p>

**\$600MM** palliative care products provide temporary symptomatic relief

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

REVENUE-BASED FORECAST ASSUMPTIONS

Potential Global Market:

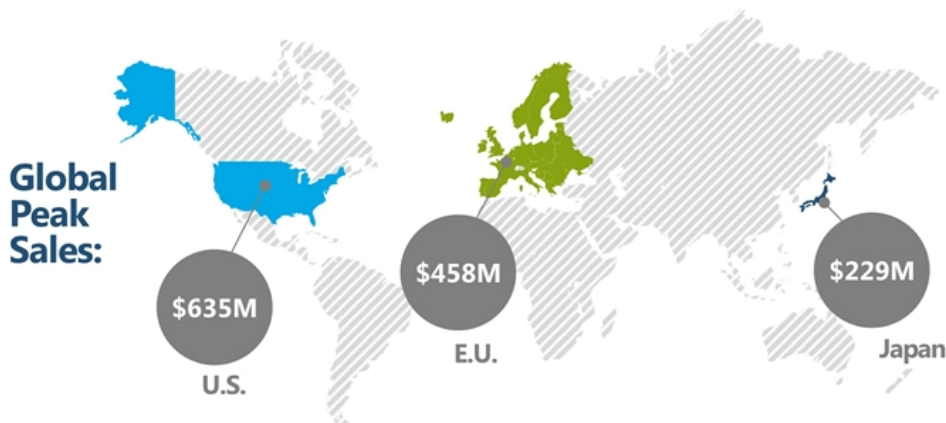
**6.2 MILLION+**  
new patients ww/yr  
(1.2MM develop OM)

Peak Share:



Cost:

**\$100**  
per day



Gross Margin:

**90%**

Intellectual property relating to AG013 extends into 2030s



## AG013: Phase 2 Study Design Agreed with FDA

- Double-blind, placebo – controlled evaluation of daily AG013 ( $2 \times 10^{11}$  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
- ~45 clinical centers in United States and Europe

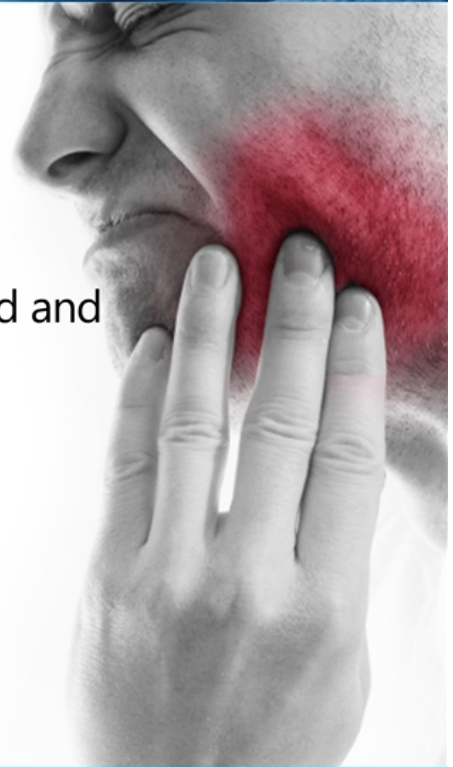
AG013  
Received  
**FDA Fast  
Track**  
Designation

- **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 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



A blue-tinted microscopic image of several rod-shaped bacteria, likely Bacillus species, showing their characteristic spore-like structures. The bacteria are in focus, with some appearing in the foreground and others blurred in the background.

**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
<b><i>Clostridium difficile</i></b>		<b>500,000</b>
Carbapenem-Resistant Enterobacteriaceae (CRE)		9,000
<i>Neisseria gonorrhoeae</i>		246,000
MDR Acinetobacter		7,300
Drug-Resistant Campylobacter		310,000
Extended Spectrum $\beta$ -lactamase Enterobacteriaceae		26,000
<b>Vancomycin-Resistant Enterococcus (VRE)</b>		<b>20,000</b>
MDR <i>Pseudomonas aeruginosa</i>		6,700
Drug-Resistant Non-Typhoid Salmonella		100,000
Drug-Resistant Typhoid Salmonella		3,800
Drug-Resistant Shigella		27,000
<b>Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)</b>		<b>80,000</b>
<b>Drug-Resistant <i>Streptococcus pneumoniae</i></b>		<b>1,200,000</b>

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

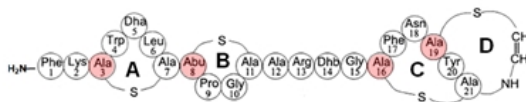
- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage lining of the colon
- 500,000 infections annually resulting in 29,000 deaths
- 83,000 will experience at least one recurrence
- Deaths have increased 400% since 2000
- Healthcare-associated infections occur: 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

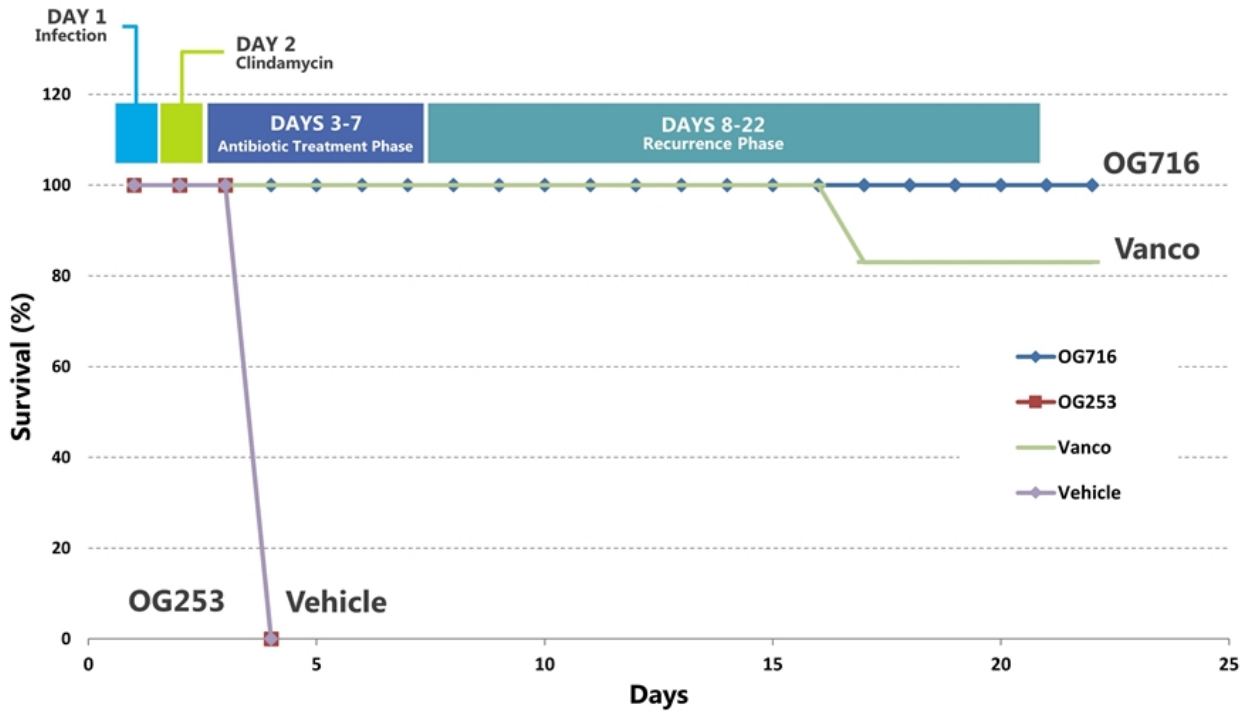
- Lantibiotics are novel class of peptide antibacterial compounds naturally produced by variety of Gram-positive bacterial strains to attack competing bacterial strains
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Prior development limited by manufacturing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



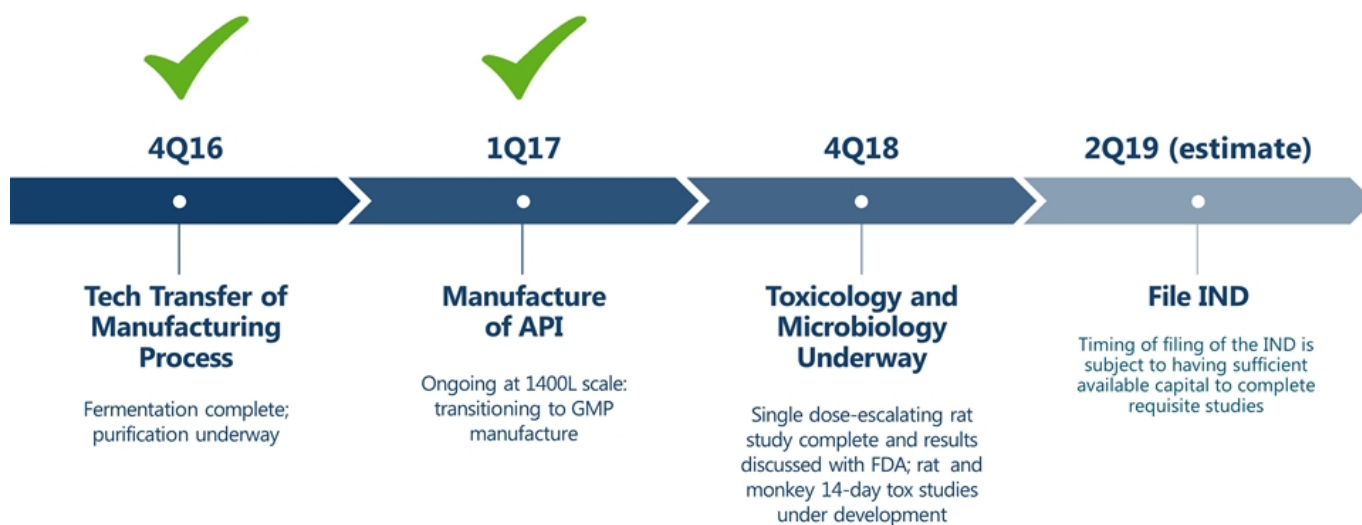
**Mutacin 1140: a lantibiotic produced by *Streptococcus mutans***



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



# Lantibiotics: OG716 *C. difficile* Program Milestones





**Corporate Status Update**

A horizontal banner with a blue background featuring a microscopic view of biological cells. The text "Corporate Status Update" is written in white, bold, sans-serif font on the left side of the banner.

# Capitalization

	<u>Common Stock Equivalents</u>	<u>Major Shareholders</u>	<u>Common Stock</u>	<u>Common Stock Equivalents</u>
<b>Common Stock Outstanding *</b>	<b>18,419,135</b>	<b>Koski Family</b>	<b>10.2%</b>	<b>6.3%</b>
<b>Series A Convertible Preferred*</b>	<b>941,701</b>	<b>Intrexon Corporation (NYSE:XON)</b>	<b>8.4%</b>	<b>3.8%</b>
<b>Series B Convertible Preferred*</b>	<b>1,320,002</b>			
<b>Series C Non-Convertible Perpetual Preferred*** (101.733 shares outstanding)</b>	<b>-</b>	<b>Other Institutional Investors</b>		
<b>Series D Convertible Preferred*</b>	<b>1,496,000</b>	<b>MSD Credit Opportunity Master Fund LP</b>		
<b>Warrants (WAEP \$1.32)*</b>	<b>16,877,425</b>	<b>Harvest Intrexon Enterprise Fund I, LP</b>		
<b>Reserved for issuance under stock incentive plan*</b>	<b>2,009,250</b>	<b>Harvest Intrexon Enterprise Fund I (AI), LP</b>		
		<b>Altium Capital Management LP</b>		
		<b>Empery Asset Management, LP</b>		
<b>Total</b>	<b>41,063,513</b>			
		<b>Pro-Forma Cash**</b>		<b>\$16.2M</b>

\* Information is as of September 30, 2018.

\*\* Information is as of June 30, 2018 plus net proceeds of ~\$12.3 million from July 2018 Underwritten Public Offering.

\*\*\* 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, C, and D 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