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

FORM 8-K

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

Date of Report: August 15, 2018
(Date of earliest event reported)

Oragenics, Inc.
(Exact name of registrant as specified in its charter)

FL	001-32188	59-3410522
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

4902 Eisenhower Boulevard, Suite 125 Tampa, FL	33634
(Address of principal executive offices)	(Zip Code)

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

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

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. ☐

Item 7.01 Regulation FD Disclosure.

On August 15, 2018, Oragenics, Inc. (the "Company") plans to make an investor presentation (the "Investor Presentation") a copy of which is attached to this report 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.oragenics.com.

By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

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.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, unless the Company specifically states that the information is to be considered "filed" under the Exchange Act or specifically incorporates it by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 8.01 Other Events.

On August 15, 2018, the Company announced it was resuming its Phase 2 clinical trial of AG013 for the treatment of Oral Mucositis following positive routine safety review. A copy of the press release announcing these events is attached as Exhibit 99.2 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation
99.2	Press Release dated August 15, 2018

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 15th day of August, 2018.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

ORAGENICS

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

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4902 Eisenhower Blvd., Suite 125
Tampa, FL 33634
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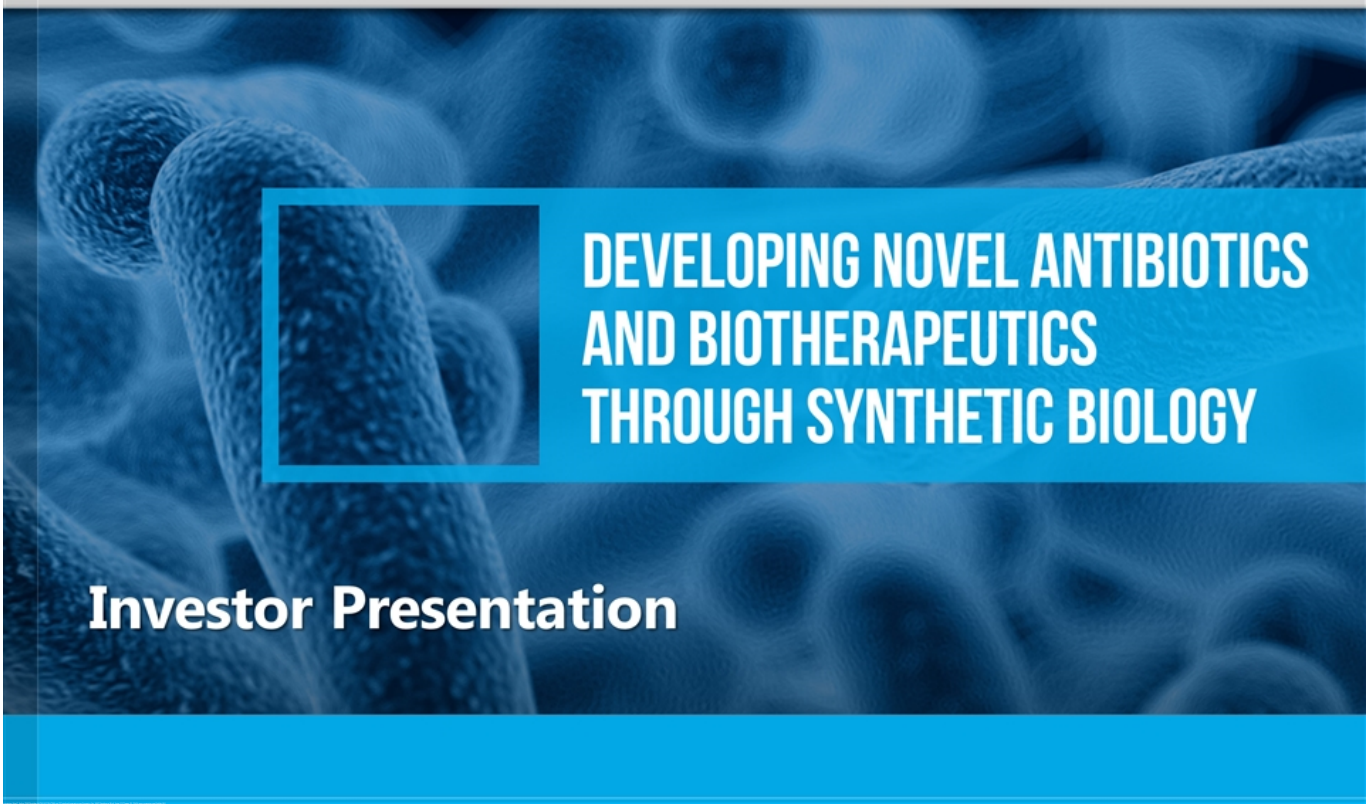

DEVELOPING NOVEL ANTIBIOTICS AND BIOTHERAPEUTICS THROUGH SYNTHETIC BIOLOGY

Investor Presentation

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

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Lantibiotics Platform: A novel class of peptide antibacterial compounds, with activity against a variety of gram(+) infections

Development Program Overview

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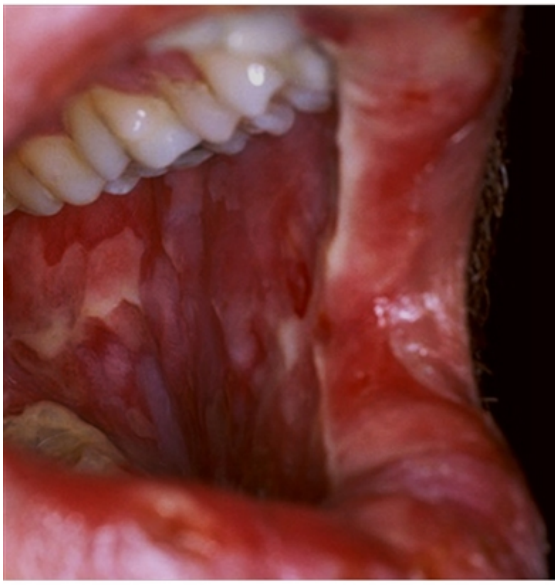
AG013: First-in-Class Therapy for Oral Mucositis

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.
- > 770,000 U.S. newly diagnosed cancer patients receiving conventional chemotherapy and radiation are at increased risk of developing OM*

*Center Disease Control, 2017

Oral Mucositis: Large Addressable Market Opportunity

No drug is approved to prevent OM in the broad cancer population; >770,000 cancer patients annually in U.S. at increased risk of developing OM*

Multiple therapies induce oral mucositis

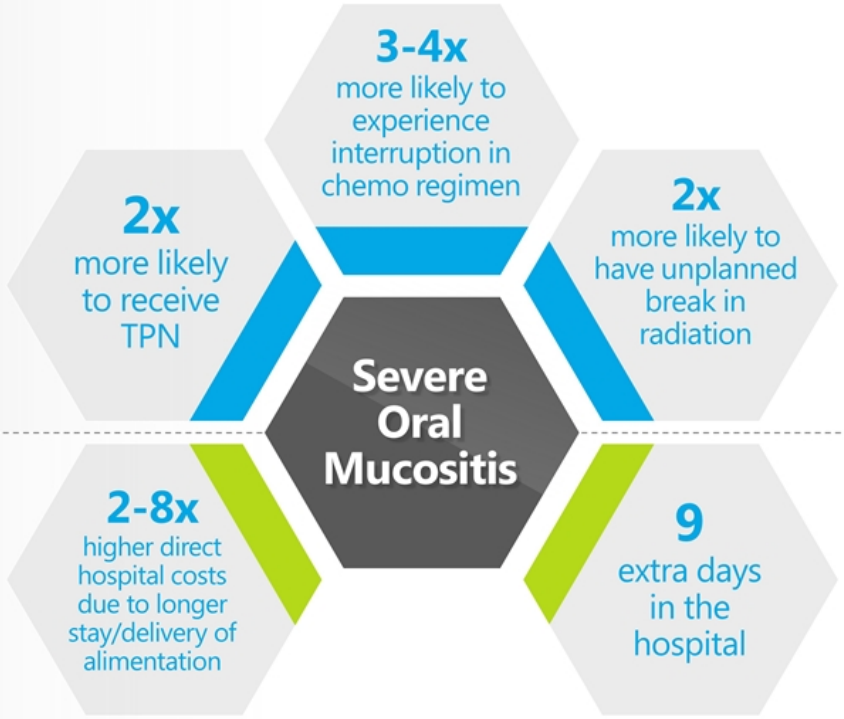
- Cisplatin (inc. Carboplatin)
- 5-Fluorouracil
- Irinotecan
- Methotrexate
- Cytarabine
- Radiation therapy in **head and neck cancer** is synergistic
- Biologics: mTOR inhibitors, including sirolimus, temsirolimus and everolimus

*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

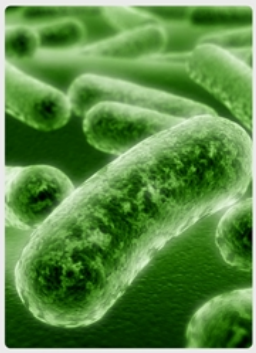
Efficacy endpoints include:

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

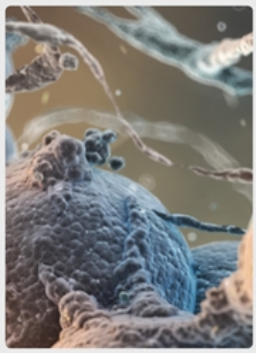
3

Patient mixes powder with a raspberry-flavored solution

4

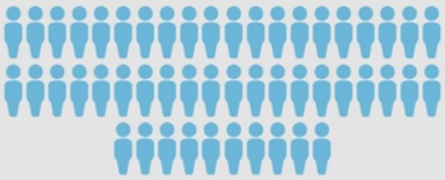
Patient swishes for 30 seconds after every meal

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 Potential for Global Peak Sales of $2.2B for Oral Mucositis

REVENUE-BASED FORECAST ASSUMPTIONS

Potential Global Market:

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

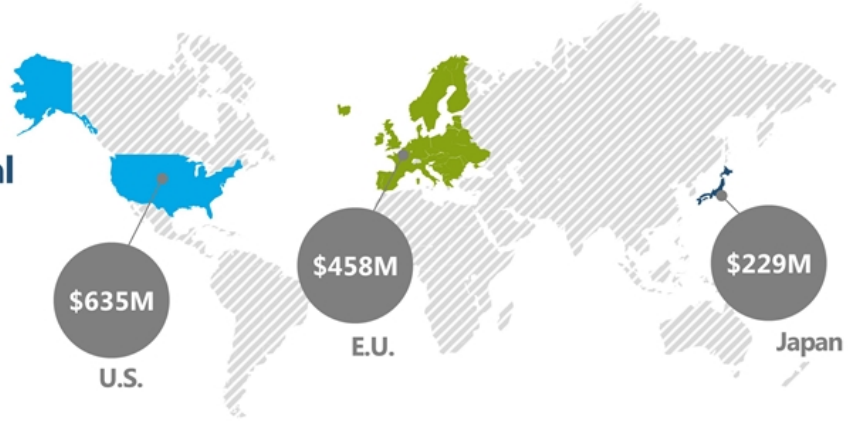
Peak Share:

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: Established Regulatory Path

- Backdrop: No approved drug to prevent **oral mucositis** in broad cancer population and current therapies are primarily palliative creates favorable regulatory environment.
- Received FDA **Fast Track** designation in November 2016
  - Frequent program interactions
  - Shorter NDA review times
  - Potential for phase 2 study to be considered one of two pivotal trials
- Granted Orphan Drug status in EU

AG013 Phase 1B Results: Safe and Effective

Exploratory Efficacy

- 35% reduction in mean number of days of ulcerative OM vs. placebo over 14-day treatment, which is the primary endpoint for Phase 2 study
- 29% (4/14) of AG013 patients had 0 or 1 day of ulcerative OM vs. 0% (0/7) placebo

Pharmacokinetics

- Live AG013 levels exist for 90 minutes post rinse
- hTFF levels similar across all doses (CFU: $2x10^{11}$ QID; TID; 6xD)
- No AG013 detected in blood

Safety

- 100% compliance for QD and TID dosing
- No drug-related discontinuations due to AEs; no drug-related SAEs
- Most common drug related adverse event (AE): Nausea

AG013 is **SAFE** & **WELL TOLERATED** in cancer patients with OM

Source: Limaye et al. Phase 1b, Multicenter, Single Blinded, Placebo-Controlled, Sequential Dose Escalation Study to Assess the Safety and Tolerability of Topically Applied AG013 in Subjects with Locally Advanced Head and Neck Cancer Receiving Induction Therapy, *Cancer* Dec. 2013: 4268-4276

AG013: Phase 2 Study Design Agreed with FDA

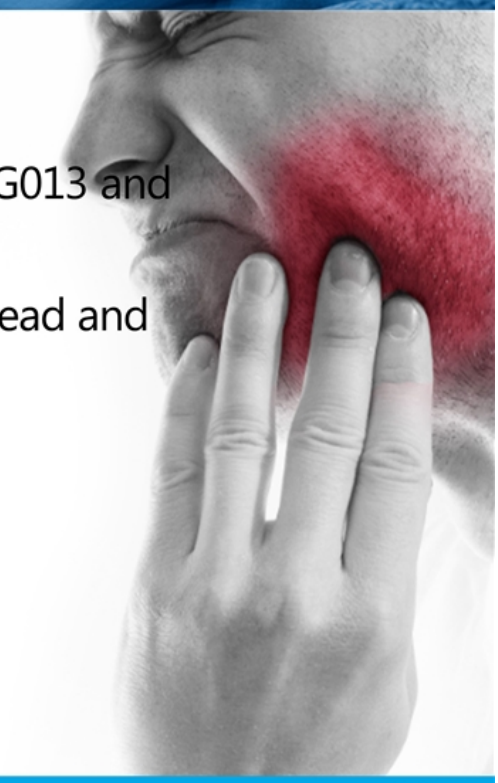
- Double-blind, placebo – controlled evaluation of daily AG013 ($2x10^{11}$ CFU) TID oral rinse for duration of cancer treatment regimen
- 160-180 evaluable patients with head and neck cancer receiving chemoradiation therapy over 7-9 weeks and standard of care for prevention of OM
- ~45 clinical centers 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

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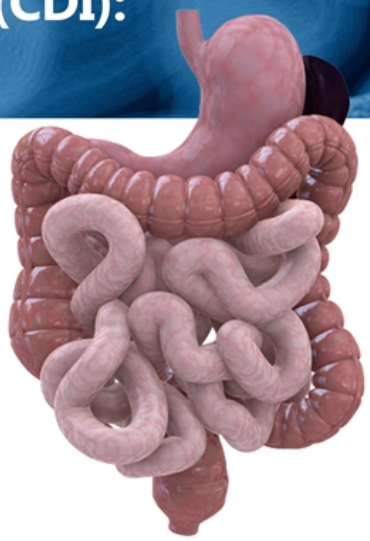
Novel Lantibiotic Platform for
Multidrug Resistant Bacterial Infections

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 pathgen 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

Competitive Overview

Currently Approved Therapies:

- Metronidazole
- Vancomycin
- Fidaxomicin
- Rifaximin
- Zinplava (monoclonal antibody)

Projected 2019 U.S. sales for *C. difficile* therapies: **$426M***

Therapies under development:

Follow-on generations of existing antibiotics, enzymes and enzyme/protein synthesis inhibitors, vaccines, microbiome/fecal transplant therapies, and toxin binding polyclonal antibodies.

* Source: GlobalData

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*

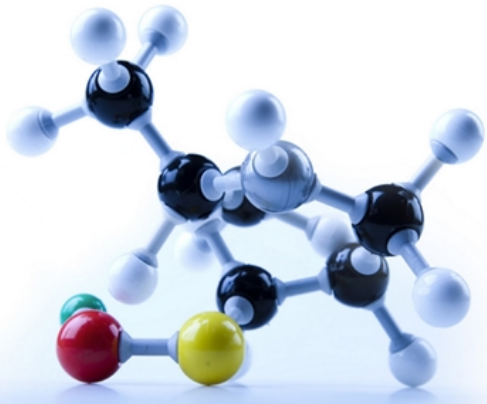
Lantibiotic Profile

Preliminary MU1140 (parent compound) preclinical data:

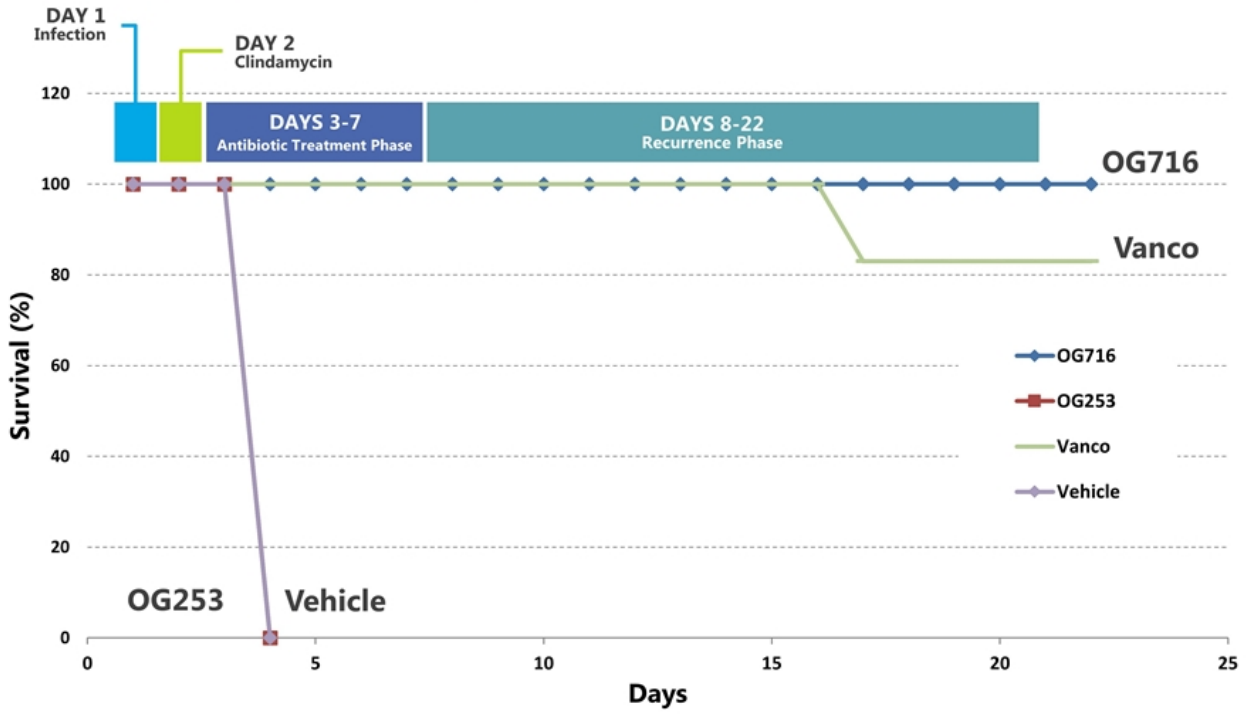
- Novel mechanism of action (unique binding to Lipid II)
- No cross-reactivity with existing classes of antibiotics
- Minimal in vitro cytotoxicity in mouse and human cell lines; minimal immunogenicity

OG716 selected as lead compound for treatment of *C. difficile* infections

- Orally active
- Microbiology profile favorably compares to previous compounds
- Potent against *Clostridium difficile* in standard animal infection model
- Intellectual property extends into late 2030s for second-generation compounds



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



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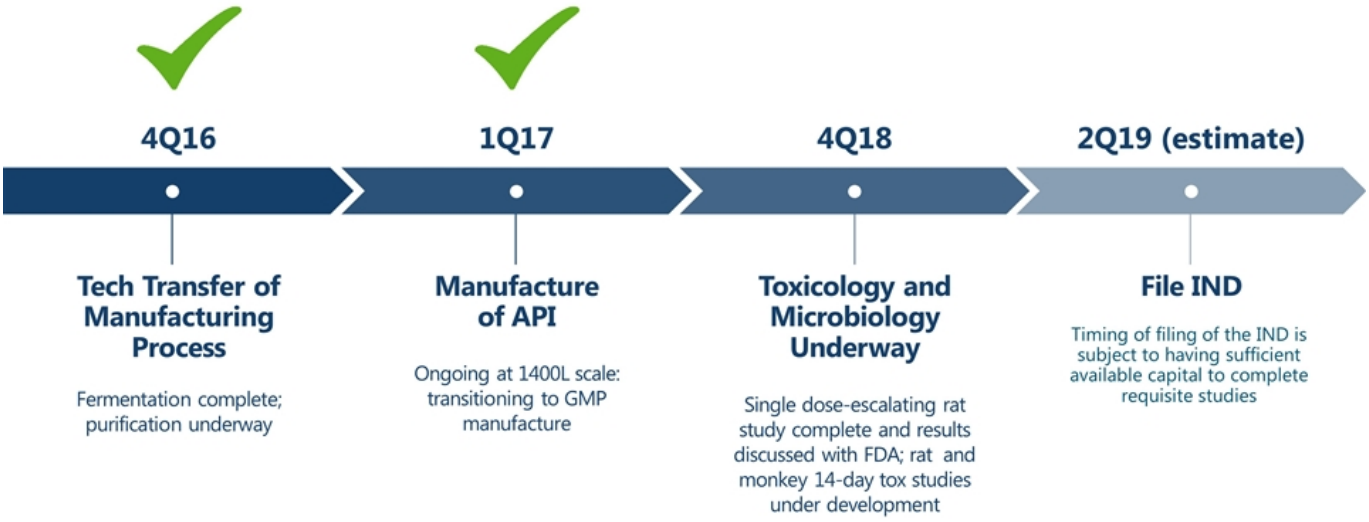
Lantibiotics: OG716 *C. difficile* Program Milestones



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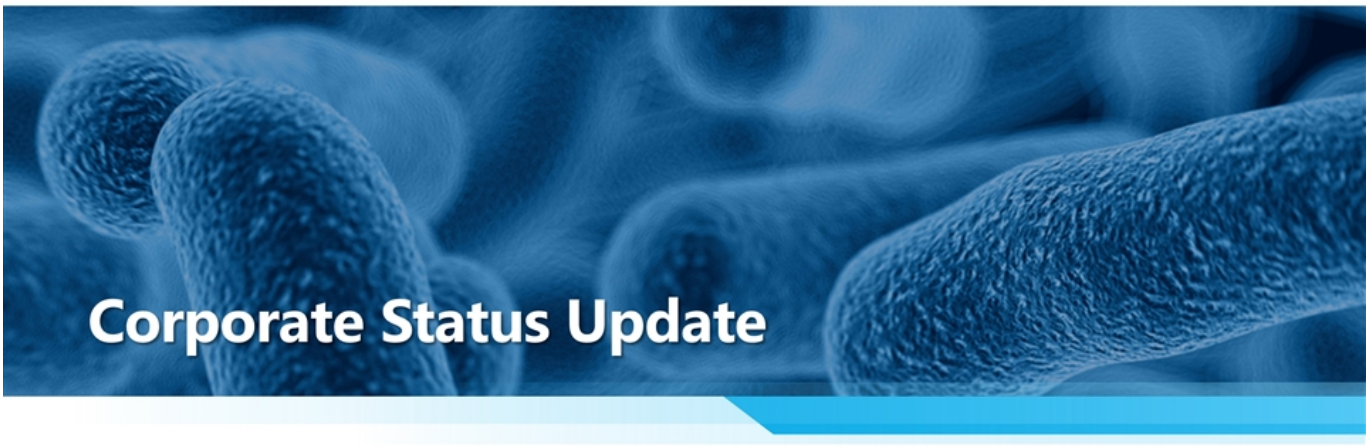

Corporate Status Update

Capitalization

	Common Stock Equivalents
Common Stock Outstanding *	11,837,635
Series A Convertible Preferred*	941,701
Series B Convertible Preferred*	1,320,002
Series C Non-Convertible Perpetual Preferred*** (101.733 shares outstanding)	-
Series D Convertible Preferred*	8,065,000
Warrants (WAEP $1.32)*	16,877,425
Options (WAEP $6.55)*	388,633
Reserved for future issuance of stock awards*	1,620,617
Total	41,051,013

Major Shareholders	Common Stock	Common Stock Equivalents
Koski Family	14.4%	5.6%
Intrexon Corporation (NYSE:XON)	13.1%	3.8%

Other Institutional Investors

- MSD Credit Opportunity Master Fund LP
- Harvest Intrexon Enterprise Fund I, LP
- Harvest Intrexon Enterprise Fund I (AI), LP
- Altium Capital Management LP
- Empery Asset Management, LP

Pro-Forma Cash**	$16.2M

* Information is as of August 8, 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

Exhibit 99.2

ORAGENICS, INC. RESUMES PHASE 2 CLINICAL TRIAL OF AG013 IN ORAL MUCOSITIS FOLLOWING POSITIVE ROUTINE SAFETY REVIEW

TAMPA, Fla., August 15, 2018 — Oragenics, Inc. (NYSE American: OGEN), a leader in the development of new antibiotics against infectious diseases and effective treatments for oral mucositis (OM), today announced it has resumed its Phase 2 clinical trial of AG013, a *live* biotherapeutic product for the potential treatment of OM following a positive review by an independent Data Safety Monitoring Board (DSMB).

"Based on the DSMB's positive review, and using funds recently raised through a public offering, we are now expanding our Phase 2 trial to up to 45 additional centers in the US and EU in order to rapidly accelerate patient enrollment," stated Alan Joslyn, president and CEO of Oragenics, Inc. "With our reinforced cash position, we look forward to completing the trial next year while concurrently advancing our lantibiotic program."

In May 2018, Oragenics reported positive interim safety analysis results based on the first 19 patients, which were evaluated on the basis of treatment-emergent adverse events, vital signs, weight, physical examination, clinical laboratory assessment and the potential presence of AG013 in blood. Tolerability measures (taste, consistency and smell) were collected from patient diaries. Following a routine data review, the trial's independent DSMB concluded that it may proceed with no necessary changes to the study.

The ongoing Phase 2 trial is a double-blind, placebo-controlled, two-arm, multi-center trial, in which approximately 200 patients will be randomized in a 1:1 ratio to receive either AG013 or placebo. The purpose of the study (NCT03234465) is to evaluate the safety, tolerability and efficacy of topically administered AG013 compared to placebo for reducing the incidence and severity of OM in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. Key measures include duration, time to development, and overall incidence of OM (World Health Organization scale) during the active treatment phase, which begins from the start of chemoradiation therapy until two weeks following its completion.

AG013, which has been granted Fast Track designation with the U.S. Food and Drug Administration and orphan drug status in Europe, is an ActoBiotics® therapeutic candidate formulated to deliver the therapeutic molecule Trefoil Factor 1 to the mucosal tissues in the oral cavity in a convenient oral rinsing solution. Trefoil Factors are a class of peptides involved in the protection of gastrointestinal tissues against mucosal damage and play an important role in subsequent repair. The compound was designed by the company's strategic partner, ActoBio Therapeutics, Inc., a wholly-owned subsidiary of Intrexon Corporation (NYSE: XON).

About Oragenics, Inc.

We are focused on becoming a leader in novel antibiotics against infectious disease and on developing effective treatments for oral mucositis. Oragenics, Inc. has established two exclusive worldwide channel collaborations with Intrexon Corporation and its subsidiaries. The collaborations allows Oragenics to accelerate the development of much needed new antibiotics that can work against resistant strains of bacteria and the development of biotherapeutics for oral mucositis and other diseases and conditions of the oral cavity, throat, and esophagus.

For more information about Oragenics, please visit www.oragenics.com.

Safe Harbor Statement: Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that reflect management's current views with respect to future events and performance. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words " believe," " expect," " anticipate," " intend," " estimate," " project" and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to, risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission. Oragenics assumes no responsibility to update any forward-looking statements contained in this press release or with respect to the matters described herein.

Oragenics, Inc.

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Chief Financial Officer
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or

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