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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: April 18, 2017**  
(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 1.01 Entry into a Material Definitive Agreement.*****Loan Commitment Letter***

On April 18, 2017, Oragenics, Inc. (the “Company”) entered into a commitment letter (the “Commitment Letter”) with Intrexon Corporation (“Intrexon”) one of our largest shareholders and our partner on certain of our development programs. The Commitment Letter provides for Intrexon to make an unsecured non-convertible loan (the “Loan”) to the Company in the principal amount of \$2.4 million. The Loan would be repayable within 24 months and carry an interest rate of 12% per annum. The funds from the Loan would be used to fund our AG013 research and clinical trials. The Loan under the Commitment Letter is conditioned upon the Company obtaining other financing of least \$2.7 million and other customary closing conditions.

The foregoing description of the Commitment Letter is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 7.01 Regulation FD Disclosure.**

On April 18, 2017, the Company intends to post an investor presentation prepared by the Company (the “Investor Presentation”) which it also expects to use from time to time in connection with presentations to potential investors, industry analysts and others. The Investor Presentation, which is available under the “Presentations” tab in the “News and Media” section of the Company’s website, located at [www.oragenics.com](http://www.oragenics.com), is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 April 18, 2017, the Company issued a press release providing an update regarding the progress of its two lead product candidates, AG013 for the treatment of oral mucositis and OG716 for the treatment of *Clostridium difficile* (“*C. diff*”). A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
10.1	Loan Commitment Letter dated April 18, 2017.
99.1	Investor Presentation
99.2	Press Release dated April 18, 2017

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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.

Dated: April 18, 2017

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

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





April 18, 2017

Oragenics, Inc.  
Attention: Alan Joslyn, CEO

Dear Dr. Joslyn:

We are pleased to advise you that Intrexon Corporation (“**Intrexon**”) hereby commits to provide Oragenics, Inc. (the “**Borrower**”) with an unsecured loan (the “**Loan**”) subject to the following terms and conditions:

1. **Loan Terms.**

(a) **Purpose:** The proceeds of the Loan will be used to fund Borrower’s AG013 research and clinical trials.

(b) **Loan amount:** \$2,400,000 which may be made in one or more tranches at the election of the Borrower.

(c) **Interest:** The interest rate charged on the outstanding principal balance of the Loan shall equal 12% per annum. All accrued and unpaid principal and interest under the Loan shall be due and payable upon the maturity date of the Loan.

(d) **Maturity Date:** Two (2) years from the date of the Closing (as defined below).

(e) **Prepayment:** Borrower may prepay the Loan in whole or in part (along with any accrued interest), without penalty or premium, at any time prior to the maturity date.

2. **Security.** The Loan will be unsecured and non-convertible.

3. **Costs and Expenses.** Each party shall pay all costs and expenses incurred by such party in connection with the Loan.

4. **Conditions to Closing.** The closing of the Loan is conditioned upon:

(a) Execution of a Note Purchase Agreement and Unsecured Promissory Note (the “**Loan Documents**”) in form acceptable to the parties.

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(b) Closing and funding of equity financing resulting in gross proceeds to Borrower of at least \$2.7 million no later than June 1, 2017.

(c) No action, suit, proceeding or investigation shall have been instituted before any court or governmental body, or instituted by any governmental agency to restrain or prevent consummation of the Loan.

5. **Commitment Binding upon Acceptance.** This commitment letter constitutes an offer to enter into the transactions described herein and upon execution by Borrower will constitute a binding contract.

6. **Closing.** The Closing shall occur concurrently with the closing of the Equity Financing and in all events, Closing shall occur not later than June 1, 2017.

7. **Miscellaneous.** Any invalidation or waiver of any of the provisions of this commitment shall not invalidate or waive any other provision hereof. This commitment and the enforcement hereof shall be construed in accordance with the laws of the State of Florida. Time is of the essence. This commitment letter constitutes the entire agreement of the parties with respect to the Loan and supersedes all previous letters, agreements or understandings with respect to the Loan. This commitment may be signed in counterparts and by facsimile or other electronic transmission which shall be considered the same as an original.

INTREXON CORPORATION

By: /s/ Donald P. Lehr  
Name: Donald P. Lehr  
Title: Chief Legal Officer

**ACCEPTED THIS 18 DAY OF APRIL, 2017**

ORAGENICS, INC.

By: /s/ Alan Joslyn  
Name: Alan Joslyn  
Title: Chief Executive Officer

# ORAGENICS

A background image of a molecular structure with various colored spheres (blue, grey, red) connected by lines, set against a light blue gradient.

Engineering New  
Antibiotics and  
Biotherapeutics Through  
Synthetic Biology

Investor Presentation

April 2017

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.

- **First-In-Class Therapy for Prevention of Oral Mucositis in Cancer Patients moving to registration-level trial in 1H 2017**
- **Novel Antibiotic Platform Capable of Treating Multi-Drug Resistant Gram (+) Infections - MRSA, *Streptococcus*, *C. difficile*, VRE**
  - Clinical trial initiation targeted for 1Q 2018
- **Key strategic technology and financial support relationship with Intrexon Corporation**

- **Oragenics Inc:** Develops novel biotherapeutics leveraging its R&D expertise with Intrexon's leading synthetic biology platform via two exclusive channel collaborations.
- **Phase 2 First-In-Class Oral Mucositis (OM) Program:**
  - No drug is approved to prevent OM in out-patient setting
  - AG013 granted Orphan Drug status in EU and received FDA Fast Track designation
  - IND update submitted March 2017
- **Novel Lantibiotics Platform:** A novel class of peptide antibacterial compounds, with activity against a variety of gram(+) infections.
  - Lead compound, **OG716**, has entered IND-enabling studies with an expected IND filing in 4Q2017 (contingent on financing)
  - FDA Pre-IND meeting feedback received April 2017

# Development Program Overview

PROGRAM	AREA	RESEARCH	IND STUDIES	PHASE 1	PHASE 2	PHASE 3	
AG013	Oral Mucositis						
OG716	<i>Clostridium Difficile</i> Infections						
Lantibiotic Library	Expand Indications						

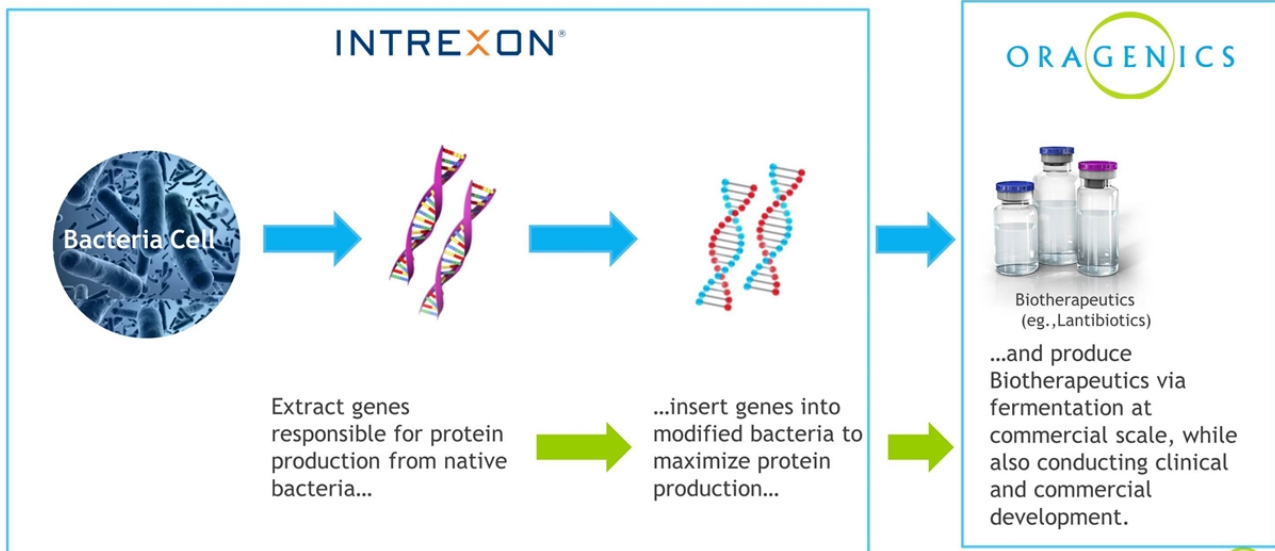
- Relationship initiated in 2012
- Significant Shareholder: Owns 30% of outstanding shares in Oragenics
- Funding Support: Provided funding for Research and Development of Product Candidates
- Synthetic Biology & gene manipulation capability for advancement of antibiotic program
- Manufacturing oversight and analytical support in oral mucositis program



# Engineering Solutions In Conjunction With Intrexon (NYSE:XON)

ORAGENICS

Engineering New Antibiotics and Biotherapeutics Through Synthetic Biology





ORAGENICS

AG013:Phase 2 Ready First-In-Class Therapy  
for Oral Mucositis

## Epidemiology for Oral Mucositis

- Most common and debilitating complication of cancer chemo and radiation therapy.
- Caused by the breakdown of mucosal lining resulting in formation of oral ulcer.
- Causes nutritional deficits due to inability to eat and drink resulting in potential alterations of cancer treatment regimens.
- Influenced by chemotherapy and/or radiation regimen - Cisplatin, 5-FU, Irinotecan.

## Market Overview

- Approximately **500,000 cases of OM in U.S.**
- Over 80% of patients with head and neck cancer commonly develop OM.



- No drug is approved to prevent OM in broad cancer population and therapies are primarily palliative.
- AG013 received FDA Fast Track designation in November 2016.
- AG013 granted Orphan Drug status in European Union.
- Oragenics has **exclusive worldwide license of AG013** from Intrexon in the treatment of OM in cancer patients.
- Intellectual Property relating to AG013 extends into 2030s

- **AG013 is a convenient raspberry 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 class of peptides involved in protecting mucosal tissues against damage and in subsequent repair
- Cost effective (low COGs) rinse provides continuous **oropharyngeal** coverage with *L. lactis* producing hTFF1
- 7-9 weeks of continuous use
  - Prevention: No grade 3 or 4 OM during chemoradiation course
  - Treatment: Reduced number of days of grade 3 or 4 OM versus comparator (standard of care)
- **FDA fast track designation** allows for frequent program interactions, shorter NDA review times and potential for phase 2 study to be considered one of two pivotal trials

# AG013 Treats the Underlying Cause of OM With a Convenient to Use Delivery System

ORAGENICS

Engineering New  
Antibiotics and  
Biotherapeutics Through  
Synthetic Biology

2017 Projected Worldwide Competitor Sales: \$974MM\*

## Therapeutic Options

- Kepivance (IV)
- Ethyol

## Marketed Palliative Products

(Oral Bleeding, Dry Mouth, Pain, Oral Decontamination)

- Gelclair
- Mugard
- NeutraSal
- Episil
- Caphosol
- Benzydamine Mouth Wash



\* source: GlobalData

## Safety:

- Most Common Drug Related Adverse Event (AE): Nausea
- No drug related discontinuations due to AEs and no drug related SAEs
- 100% compliance for QD and TID dosing

## Pharmacokinetics:

- Live AG013 levels exist for 90 minutes post rinse
- hTFF levels similar across all doses (CFU:  $2 \times 10^{11}$  QID; TID; 6xD)
- No AG013 detected in blood

## Exploratory Efficacy:

- 35% reduction in mean number of days of ulcerative OM vs. placebo  
[Note: this endpoint is the primary endpoint for the Phase 2 study]
- 29% of AG013 patients had 0 or 1 day of ulcerative OM vs 0% placebo

AG013 IS SAFE AND  
WELL TOLERATED  
WHEN GIVEN TO  
CANCER PATIENTS  
WITH OM

- Double-Blind, Placebo - Controlled Evaluation of daily AG013 ( $2 \times 10^{11}$  CFU) TID oral rinse for the duration of the cancer treatment regimen
- 160-180 patients with Head and Neck cancer receiving chemoradiation therapy over 7-9 weeks and standard of care for prevention of oral mucositis
- 35 clinical centers in the United States and Europe
- **Primary efficacy endpoint:** Duration (in days) of severe oral mucositis (WHO grades 3 & 4)
- **Sample size Consideration:** A sample of 160 evaluable patients (80 /group) will provide 80% power to detect a 5 day difference between groups with respect to severe oral mucositis
- A number of secondary endpoints, including number of OM free (WHO grades 1 & 2) days, time to onset of OM, use of pain meds, alteration in cancer regimens due to OM etc. will also be evaluated

AG013 Program,  
including Phase 2  
protocol, has been  
developed with  
FDA and received  
Fast Track  
Designation



# AG013: Timeline of Key Events



Received: August 12, 2016

Initiated: August 26, 2016

A laboratory setting with a pipette, a microplate, and various glassware. The word 'ORAGENICS' is overlaid in blue text, with the 'O' circled in a green ring.

ORAGENICS

Novel Lantibiotic Platform for Serious Life-Threatening Gram(+) Bacterial Infections

- Lantibiotics are **novel class** of peptide antibacterial compounds naturally produced by variety of Gram-positive bacterial strains to attack competing bacterial strains.
- **Platform:** More than >50 lantibiotics identified, potentially creating a pipeline of new compounds to target resistant infections.
- Prior development has been limited by technological hurdles, primarily on commercial scale production, whereby the Intrexon collaboration resulted in a manufacturing solution.
- Platform provides potential for development in multidrug resistant gram(+) infections including Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant Enterococci (VRE) and virulent *Clostridium difficile*.



Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

Oragenics is developing a pipeline of lantibiotics through a collaboration with Intrexon that allows for production at commercial scale. The collaboration has already:

- ✓ Produced a significant increase in production titer yield.
- ✓ Enabled development of robust purification methods compared to traditional approaches.
- ✓ Identified second generation compounds that maintain activity following oral administration.
- ✓ Oragenics has selected lead compound OG716 and working towards 4Q2017 IND filing.

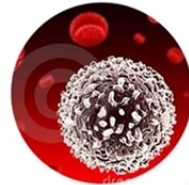
- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage the lining of the colon.
- 500,000 infections annually resulting in 29,000 deaths.
- 83,000 will experience at least one recurrence.
- Deaths have increased 400% since 2000.
- Health care associated infections 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 *C. difficile* infections are associated with onset of concomitant Vancomycin Resistant Enterococci (VRE) infection.



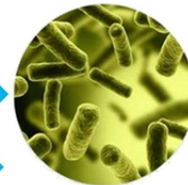
Primary bacterial infection treated with  
Cephalosporin, Ampicillin/Amoxicillin  
Clindamycin, Fluroquinolones,  
Aminoglycosides



Disrupt Gastrointestinal  
Microbiome



Develop *Clostridium  
difficile* Infection



Spores

Produces  
Toxins  
A&B

Relapse

Infect New  
Patient

Inflammation &  
Diarrhea

## Currently Approved Therapies:

- Metronidazole
- Vancomycin
- Fidaxomicin
- Rifaximin

## 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.



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

# OGEN's Discovery and Initial Characterization of Mutacin-1140 (MU1140)

- Seminal work on MU1140 (native molecule) suggested lantibiotic activity against essentially all clinically-relevant Gram (+) bacteria, including:
  - Methicillin-resistant *Staphylococcus aureus* (MRSA)
  - Vancomycin-resistant Enterococcus (VRE)
  - *Clostridium difficile* (C. diff)
- Preliminary preclinical data suggested that MU1140 had:
  - A **novel mechanism** of action
  - **No cross-reactivity** with existing classes of antibiotics
  - Minimal cytotoxicity in vitro using mouse and human cell lines; **minimal immunogenicity**
  - **Synergy** with aminoglycosides





## MU1140



- Difficulty with expansion of fermentation/purification process
- Unable to manufacture sufficient quantities to test therapeutically

## OG253

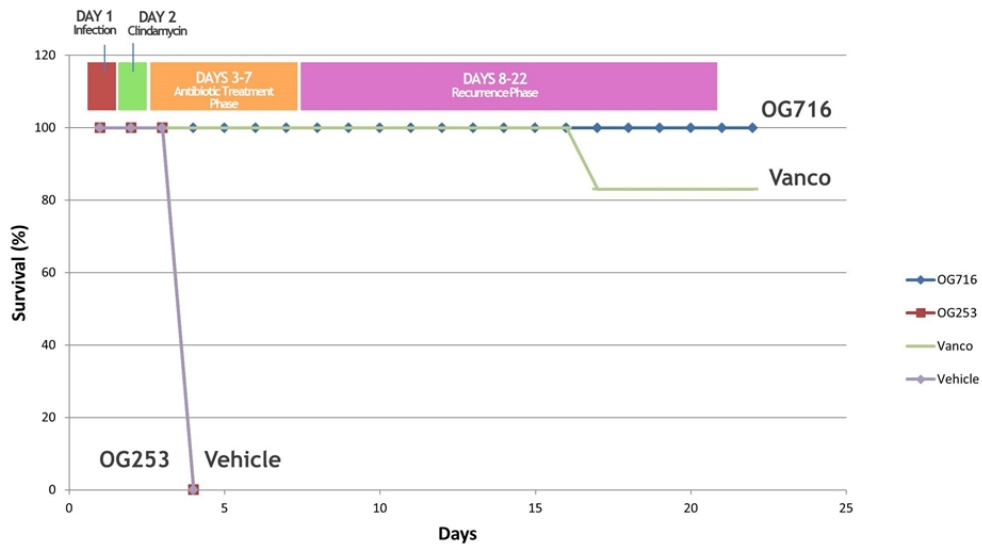


- Unstable in gastric and small intestinal fluid
- Requires specific colonic delivery

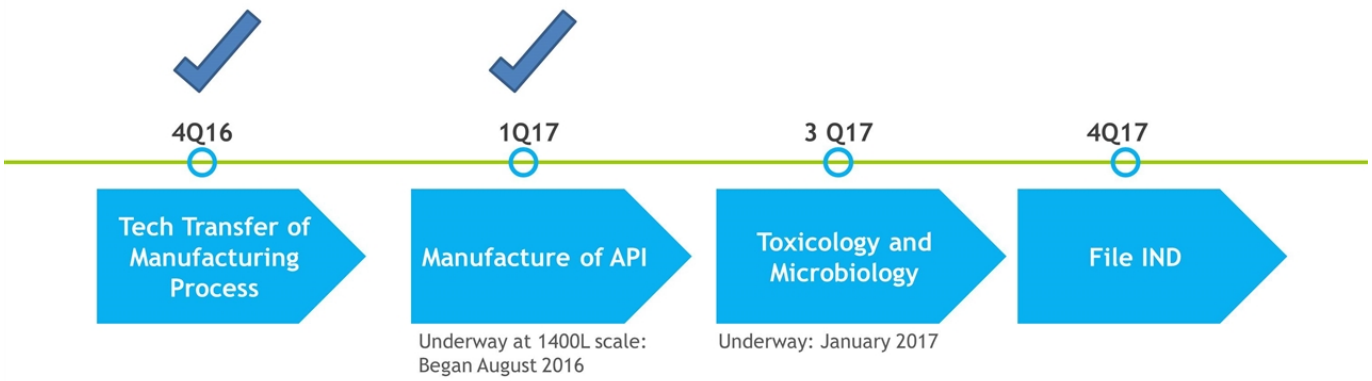
## OG716

- Orally active without special formulation needs
- Microbiology profile favorably compares to previous compounds
- Intellectual Property relating to OG716 should extend into the late 2030s

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



# Lantibiotics: Second Generation Program Milestones



## 2017 Milestones:

- 1Q: Successful FDA pre-IND meeting for OG716 lantibiotic (**Complete April 2017**)
- 1H: Anticipate treatment of first patient in AG013 Phase 2 study
- 4Q: Complete Interim Safety Review of first 20 patients enrolled at 5 clinical sites in AG013 Phase 2 study
- 4Q: Initiate at additional 30 clinical sites to enroll remaining 140 patients in AG013 Phase 2 Protocol
- 4Q: Announce filing of OG716 IND for treating *Clostridium difficile* Infection

## 2018 Milestones:

- 2Q: Identify lantibiotic homolog to treat parenteral gram (+) infections, transition to IND enabling studies
- 3Q: Complete OG716 Phase 1 clinical studies as safe and transition to Phase 2A
- 4Q: Announce results of AG013 Phase 2 oral mucositis clinical study

**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

## DR. FREDERICK W. TELLING, Chairman of the Board of Directors

- Retired from Pfizer Inc. in June 2007 after 30 years of service, where he served as Corporate Vice President and Vice President of Corporate Strategic Planning and Policy.
- Holds a B.A. in History and Economics from Hamilton College, a MA in Industrial and Labor Relations and a PhD in Economics and Public Policy from Cornell University.
- Brings to the Board an extensive array of business and industry experience as well as experience as a director of public companies.

## CHARLES L. POPE, Director

- Served as the Chief Financial Officer of Palm Bancorp, Aerosonic, Reptron, Innovaro, and SRI/Surgical Express.
- Also served as a Partner in the Audit and Financial Advisory Consulting Divisions and was a Partner in the Accounting and SEC Directorate at PricewaterhouseCoopers LLP.
- Holds a B.S. in Economics and Accounting from Auburn University and is a Certified Public Accountant in Florida.
- Brings to the Board over three decades of experience in the finance and accounting fields. In addition, Mr. Pope also has experience serving as a director of public companies.

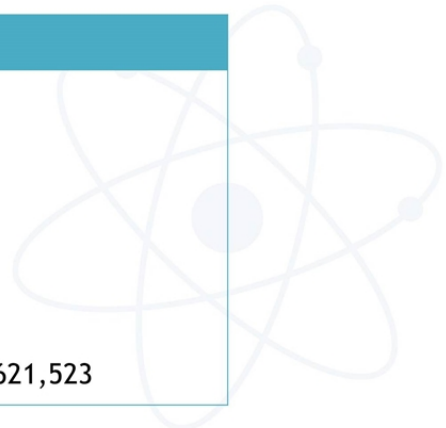
## DR. ALAN W. DUNTON, Director

- Currently the Senior Vice President of Research and Development at Purdue Pharma and the principal owner of Danerius, LLC, a biotechnology consulting company which he founded in 2006.
- Also a Director at Palatin (AMEX: PTN) and Targacept (NASDAQ: TRGT).
- Holds a MD from New York University School of Medicine, where he completed his residency in internal medicine. He also was a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center.

## ROBERT C. KOSKI, Director

- Practiced as an attorney with the Koski Firm, a sole proprietorship since 1992, where his practice includes litigation and tax law.
- Holds a B.A. in Philosophy and English from Colgate University, a JD from Emory School of Law and an LLM in Taxation and Litigation from Emory University.
- Brings to the Board over two decades of experience in the legal field as a practicing attorney. In addition to his legal experience, Mr. Koski's educational background provides a foundation for leadership and consensus-building.

	NYSE MKT	OGEN.BC
Share Price*		\$0.44
Market Cap		\$21.65M
Shares Outstanding*		49,274,219
Cash**		\$4.1M
Debt**		\$66,400
Warrants & Options**		175,584   1,621,523





A background image of a molecular structure with various colored spheres (blue, grey, red) connected by lines, set against a light blue gradient.

# ORAGENICS

Engineering New  
Antibiotics and  
Biotherapeutics Through  
Synthetic Biology

Thank You

Alan Joslyn, CEO  
[ajoslyn@oragenics.com](mailto:ajoslyn@oragenics.com)  
(813) 286-7900 X232  
4902 Eisenhower Blvd; Suite 125  
Tampa, FL 33634

### Oragenics Provides First Quarter 2017 Update

TAMPA, Florida April 18, 2017 (BUSINESS WIRE) — Oragenics, Inc. (NYSE MKT:OGEN.BC), a clinical stage biotechnology company, today announced an update on the Company's first quarter 2017 progress regarding its two product candidates, AG013 for the treatment of oral mucositis and OG716 for the treatment of *Clostridium difficile* ("*C. diff*").

With respect to our lead clinical candidate, AG013, Oragenics has submitted an Investigational New Drug ("IND") amendment for the upcoming Phase II trial. We provided the U.S. Food and Drug Administration ("FDA") with the updated protocol for the AG013 Phase II trial, including the identification of the trial sites in the United States and the manufacturing details of the product material.

AG013 is an ActoBiotics™ therapeutic candidate formulated as a convenient oral rinsing solution and designed by our strategic collaboration partner Intrexon Corporation ("Intrexon") to deliver the therapeutic molecule Trefoil Factor 1 to the mucosal tissues in the oral cavity. 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. AG013 received FDA Fast Track designation in November 2016, which we believe further validates our science as well as highlights the serious need for a treatment for oral mucositis.

Our partner Intrexon has provided a commitment letter for an unsecured \$2.4 million loan to further the clinical development of AG013 that will mature in 24 months, bear interest at 12% per annum, and is conditional on Oragenics raising an additional \$2.7 million in gross proceeds. Upon securing this additional financing, the Company will be positioned to initiate its Phase II trial for AG013 for the treatment of oral mucositis and promptly commence patient enrollment.

Alan Joslyn, Oragenics' Chief Executive Officer, commented, "We are pleased that our partner Intrexon continues to recognize the tremendous potential value in our AG013 product candidate through its continued support of the Company. We look forward to advancing our product portfolio to and through the clinic helping lead Oragenics to success."

Oragenics' second clinical candidate is the lantibiotic OG716 for the treatment of *C. diff* developed through an Exclusive Channel Collaboration with Intrexon. *C. diff* is a bacterial infection that most commonly affects older adults in hospital and long-term care facilities after they receive an antibiotic administration, although there is an increasing rate of infection in younger, healthier populations. *C. diff* is now associated with nearly 500,000 infections annually in the United States., resulting in 29,000 deaths.

We recently completed a successful pre-IND meeting for OG716 with the FDA. The agency confirmed that the clinical development plan based on the data obtained from preclinical studies, toxicity studies and manufacturing are appropriate to support the IND filing, thus paving a clear pathway to bring the first lantibiotic to treat this severe unmet medical need into the clinic.

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## About Orogenics, Inc.

We are focused on becoming a world leader in novel antibiotics against infectious disease and on developing effective treatments for oral mucositis. Orogenics, Inc. has established two exclusive worldwide channel collaborations with Intrexon Corporation, a synthetic biology company. The collaborations allow Orogenics access to Intrexon's proprietary technologies toward the goal of accelerating 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 Orogenics, please visit [www.rogenics.com](http://www.rogenics.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, our current need for financing to meet our operational needs and to be able to move our product candidates forward through pre-clinical and clinical development, our inability to obtain sufficient financing to conduct our business; any inability to obtain or delays in the Food and Drug Administration approval for future clinical studies and testing, the future success of our studies and testing and any inability to also achieve favorable results in human studies, our ability to successfully develop and commercialize products, the financial resources available to us to continue research and development, any inability to regain compliance with the NYSE MKT continued listing requirements and those other factors described in our filings with the U.S. Securities and Exchange Commission. Any responsibility to update forward-looking statements is expressly disclaimed.

Orogenics, Inc.  
Corporate:  
Michael Sullivan, 813-286-7900  
Chief Financial Officer  
[msullivan@rogenics.com](mailto:msullivan@rogenics.com)  
or

Investor/Media Relations:  
The Ruth Group  
Tram Bui 646-536-7035  
[tbui@theruthgroup.com](mailto:tbui@theruthgroup.com)