
**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: January 31, 2017
(Date of earliest event reported)

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

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)

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))
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Item 7.01 Regulation FD Disclosure.

On January 31, 2017, the Company intends to post an investor presentation prepared by the Company on the Bio CEO & Investor Conference website (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, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation

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 31st day of January , 2017.

ORAGENICS, INC.
(Registrant)

BY: /s/ Michael Sullivan
Michael Sullivan
Chief Financial 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

January 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**
- **Novel Antibiotic Platform Capable of Treating Multi-Drug Resistant Gram (+) Infections - MRSA, *Streptococcus*, *C. difficile*, VRE**

- **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
 - Planning IND update in early 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

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						

ORAGENICS + INTREXON®



Biotherapeutics
(eg., Lantibiotics)

Extract genes
responsible for protein
production from native
bacteria...



...insert genes into
modified bacteria to
maximize protein
production...



...and produce
Biotherapeutics
via fermentation
at commercial
scale.



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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 convenient 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
- T.I.D. 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)

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:

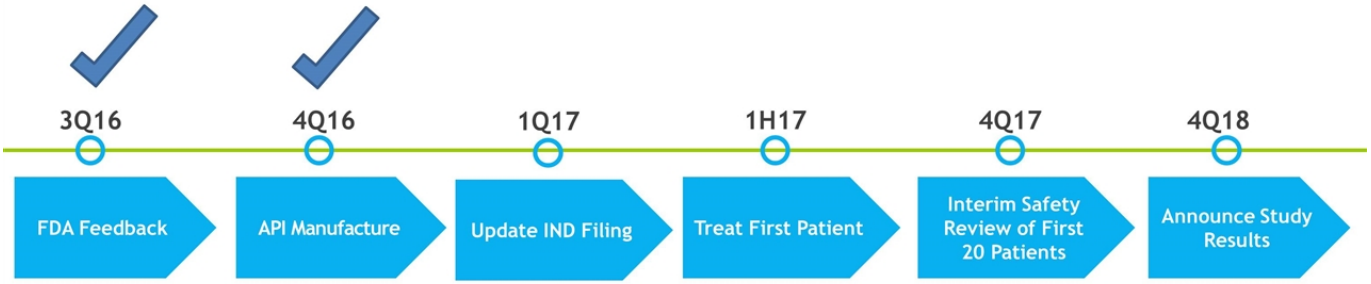
- Live AG013 levels exist for 90 minutes post rinse
- hTFF levels similar across all doses (CFU: 2×10^{11} QID; TID; 6xD)
- No AG013 detected in blood

Exploratory Efficacy:

- 35% reduction in mean number of days of ulcerative OM vs. placebo
- 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

AG013: Timeline of Key Events



Received: August 12, 2016

Initiated: August 26, 2016

A laboratory setting with a pipette being used to transfer liquid into a multi-well microplate. In the background, there are various glassware including a graduated cylinder with markings from 100 to 500, and several beakers. The scene is dimly lit, focusing on the central activity.

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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.

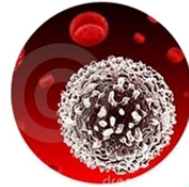
- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage the lining of the colon.
- 500,000 infections annually resulting in 29,000 deaths.
- 83,000 will experience at least one recurrence.
- Deaths have increased 400% since 2000.
- Health care associated infections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



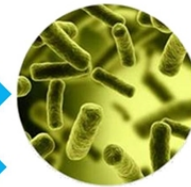
Primary bacterial infection treated with
Cephalosporin, Ampicillin/Amoxicillin
Clindamycin, Fluroquinolones,
Aminoglycosides



Disrupt Gastrointestinal
Microbiome



Develop *Clostridium
difficile* Infection



Spores



Relapse

Infect New
Patient

Produces
Toxins
A&B



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*

- 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

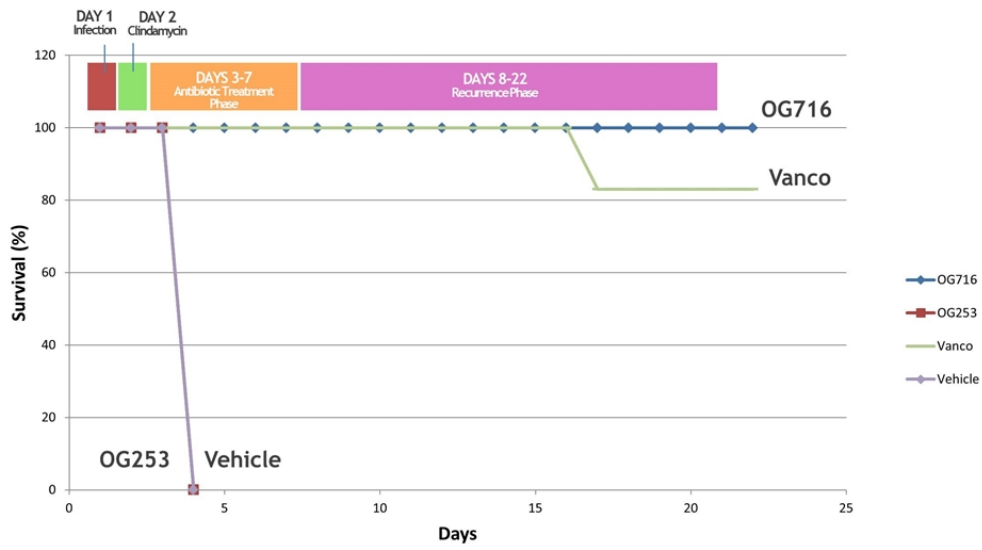


- Unstable in gastric and small intestinal fluid
- Requires specific colonic delivery

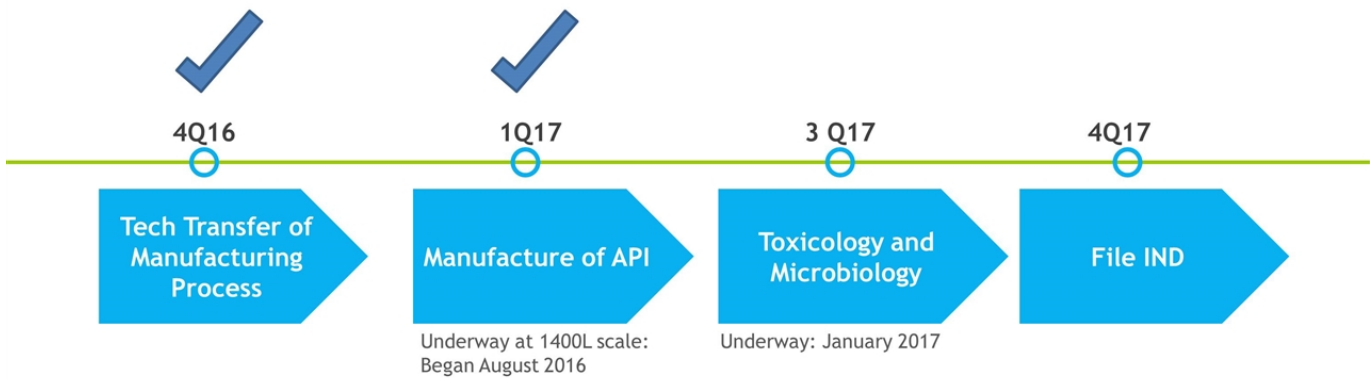
OG716

- 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
- 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 20 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.

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

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Thank You