
**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: October 22, 2019
(Date of earliest event reported)

Orogenics, 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)

(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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	OGEN	NYSE American

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 October 22, 2019, Oragenics, Inc. (the “Company”) issued a press release announcing that the Company will present and meet with investors at the BIO Investor Forum in San Francisco on October 23, 2019 and will make an investor presentation (the “Investor Presentation”). The Company also expects to use the Investor Presentation from time to time thereafter in connection with presentations to potential investors, industry analysts and others. Copies of the press release and updated Investor Presentation are attached hereto as Exhibit 99.1, and 99.2, respectively, and are incorporated herein by reference. Additionally, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated October 22, 2019.
99.2	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 22nd day of October, 2019.

ORAGENICS, INC.
(Registrant)

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



ORAGENICS, INC. TO PRESENT AT THE BIO INVESTOR FORUM

TAMPA, Fla., October 22, 2019 — 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 will be presenting at the BIO Investor Forum in San Francisco.

The company will present to investors on October 23, 2019 at 2:30 PM ET in the Yorkshire Room of Westin St. Francis in San Francisco. The BIO Investor Forum will be held October 22-23, 2019.

Further details of the company's financial filings can be found by accessing the United States Securities and Exchange Commission website at www.sec.gov.

About AG013

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 Lantibiotics

Lantibiotics are a class of antibiotic compounds with novel mechanism of action, prized for their ability to overcome antibiotic-resistant infections. With resistant strains on the rise, particularly healthcare-acquired infections (HAI), the need for these potent lantibiotic agents is critical. Oragenics is pursuing the commercial-scale production of a lantibiotic for use as an antimicrobial.

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.

Corporate:

Michael Sullivan, 813-286-7900
Chief Financial Officer
msullivan@oragenics.com

or

Investors:

John Marco
Managing Director
CORE IR
310-819-2948
johnm@coreir.com

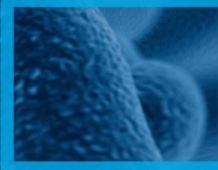
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**DEVELOPING NOVEL ANTIBIOTICS
AND BIOTHERAPEUTICS
THROUGH SYNTHETIC BIOLOGY**

Investor Presentation

NYSE American: OGEN

Safe Harbor Statement

Certain statements made in this presentation include forward-looking actions that Oragenics, Inc. ("Oragenics," or the "Company") anticipates based on certain assumptions. These statements are indicated by words such as "expect", "anticipate", "should" and similar words indicating uncertainty in facts, figures and outcomes. Such statements are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. While Oragenics believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such statements will prove to be correct. The risks associated with the Company are detailed in the Company's various reports filed by the Company with the Securities and Exchange Commission.

Investment Highlights

1

Ongoing clinical program in a ~\$20MM market cap company with near-term catalysts and sufficient cash through 2020

2

AG013 for Oral Mucositis: Large unmet clinical need - no drug is approved to **prevent OM** in the broad cancer population;

Addressable Population: > 770,000 cancer patients annually in the US

3

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



A horizontal banner with a blue background showing a microscopic view of cells. The text is overlaid on the left side of the banner.

**AG013: First-in-Class Therapy for
Prevention of 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:

2x
more likely
to receive
TPN

3-4x
more likely to
experience
interruption in
chemo regimen

2x
more likely to
have unplanned
break in
radiation

**Severe
Oral
Mucositis**

Economic Impact:

2-8x
higher direct
hospital costs
due to longer
stay/delivery of
alimentation

9
extra days
in the
hospital

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

Economic and Clinical Impact of Severe OM

TABLE 3
Estimated Costs of Cancer Treatment-related Toxicities Reported by the Northwestern University Costs of Cancer Program*

Treatment-related Toxicity (Reference)	Oncology Treatment	Cancer Diagnosis	No. of Patients	Medical Costs, \$
Mucositis/pharyngitis (current study)	Radiochemotherapy	Non-small cell lung cancer	40	25,060
Neutropenia treated as an inpatient (Albain 2002 ⁹)	Chemotherapy	Lymphoma	11	17,869
Mucositis/pharyngitis (current study)	Radiochemotherapy	Head and neck cancer	99	17,244
Neutropenia treated as an inpatient (Albain 2002 ⁹)	Chemotherapy	Breast cancer	5	10,534
Neutropenia treated as an inpatient (Albain 2002 ⁹)	Chemotherapy	Lung cancer/multiple myeloma	12	10,311
Neutropenia (Calhoun 2001 ³)	Cis-platinum	Ovarian cancer	26	7546
Febrile neutropenia (Calhoun 2003 ¹⁰)	Liposomal daunorubicin	AIDS-related Kaposi sarcoma	166	7138
Febrile neutropenia (Calhoun 2003 ¹⁰)	Liposomal doxorubicin	AIDS-related Kaposi sarcoma	121	6717
Neutropenia treated as an outpatient (Albain 2002 ⁹)	Chemotherapy	Breast cancer	17	5704
Anemia (Salma 2007 ¹¹)	Topotecan	Ovarian cancer	120	5181
Neutropenia (Salma 2007 ¹¹)	Topotecan	Ovarian cancer	120	3756
Thrombocytopenia (Calhoun 2001 ³)	Cis-platinum	Ovarian cancer	15	3268
Febrile neutropenia treated in an emergency room (Courtney 2007 ¹²)	Chemotherapy	Various	48	1455
Neutropenia treated as an outpatient (Albain 2002 ⁹)	Chemotherapy	Lung cancer/multiple myeloma	14	1329
Neutropenia treated as an outpatient (Albain 2002 ⁹)	Chemotherapy	Lymphoma	12	1201
Neuropathy (Calhoun 2001 ³)	Cis-platinum	Ovarian cancer	42	688
Palmar-plantar erythrodygia (Salma 2007 ¹¹)	Liposomal doxorubicin	Ovarian cancer	115	104
Stomatitis/esophagitis (Salma 2007 ¹¹)	Liposomal doxorubicin	Ovarian cancer	120	101
Nausea and vomiting (Salma 2007 ¹¹)	Topotecan	Ovarian cancer	120	83
Diarrhea (Salma 2007 ¹¹)	Topotecan	Ovarian cancer	120	58

AIDS indicates acquired immunodeficiency syndrome.

* Calhoun JA, Bennett CL. Evaluating the total costs of cancer. The Northwestern University Costs of Cancer Program. *Oncology* (Williston Park). Jan 2003;17(1):109-114; discussion 119-121.¹⁸

AG013: Target Product Profile

- Convenient, flavored oral rinsing solution composed of genetically modified *Lactococcus lactis* (non-pathogenic 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) delivery system provides daily continuous oropharyngeal coverage with *L. lactis* producing hTFF1 during entire cancer treatment regimen

Intellectual Property:

Intellectual property relating to AG013 extends into 2030s
Additional protections support underlying gene transfer technologies



AG013 in Action

1



AG013 delivers hTTF1 via genetically modified lactococcus

2



The bacteria is freeze-dried into vials

3



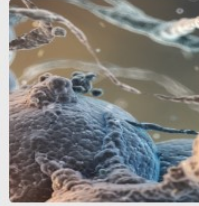
Patient mixes powder with a raspberry-flavored solution

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 <small>(indicated only for bone marrow transplant induction chemo patients)</small>
Method	 Oral topical delivery, outpatient	 Intravenous, inpatient

\$600MM palliative care products provide temporary symptomatic relief

AG013 Treats a Large Addressable Market With Potential W.W. Cumulative Sales >\$2.0Bn for Oral Mucositis

REVENUE-BASED FORECAST ASSUMPTIONS

Potential Addressable Patients Global Market:

6.0 MILLION+
new patients ww/yr

Estimated Peak Share:



Estimated Cost:

\$90
per day



Treatment Days:
~70

Gross Margin:
90%

AG013: Current Study Design Agreed with FDA

- Double-blind, placebo – controlled evaluation of daily AG013 (2×10^{11} CFU) T1D oral suspension 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
- ~59 clinical centers in United States and Europe
- **Primary efficacy endpoint:** Duration (in days) of severe OM (WHO grades 3 (unable to eat) & 4 (unable to drink))
- **Sample size consideration:** 160 evaluable patients (80/group) provides 80% power to detect 5-day difference between groups with respect to severe OM
- **OM secondary endpoints:** number of OM free (WHO grades 1 & 2) days, time to onset, use of pain medication, alteration in cancer regimens; emergency room visits for SOM

AG013
Received
FDA Fast
Track
Designation

AG013: Near Term News Flow

- 3Q19: Clinical Trial as of Oct. 15, 2019: 180 of 200 patients randomized
- 3Q19: Successful Poster presentation of ongoing clinical trial at European Society of Medical Oncology (ESMO) meeting in Barcelona, Spain September 29 - Oct 2.
- 4Q19: Anticipated announcement indicating ongoing clinical study in Head & Neck cancer patients has completed enrollment.
- **1Q20: Expected Release of topline data from ongoing clinical trial.**

A blue-tinted microscopic image of several rod-shaped bacteria, likely Bacillus species, showing their characteristic spore chains. The bacteria are in sharp focus against a blurred 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
<i>Clostridium difficile</i>		500,000
Carbapenem-Resistant Enterobacteriaceae (CRE)		9,000
<i>Neisseria gonorrhoeae</i>		246,000
MDR Acinetobacter		7,300
Drug-Resistant Campylobacter		310,000
Extended Spectrum β -lactamase Enterobacteriaceae		26,000
Vancomycin-Resistant Enterococcus (VRE)		20,000
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
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)		80,000
Drug-Resistant <i>Streptococcus pneumoniae</i>		1,200,000

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



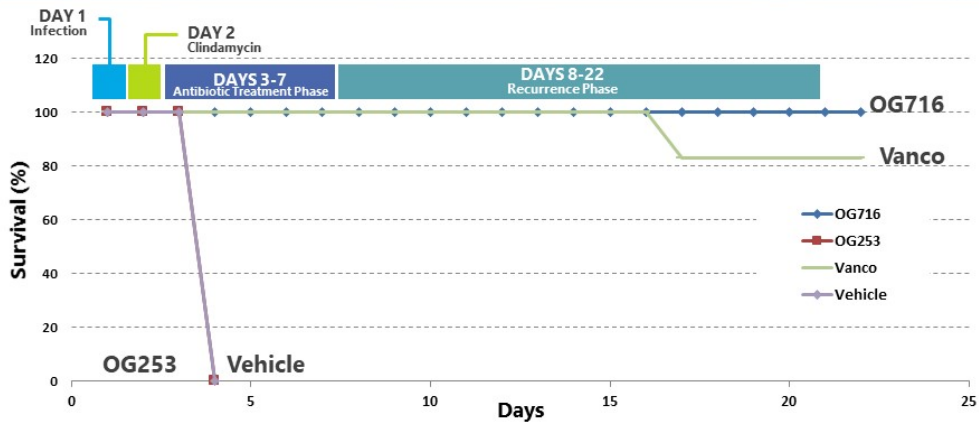
Lantibiotics: Novel Platform of Antibiotics to Treat Serious Life-Threatening Infections

- 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

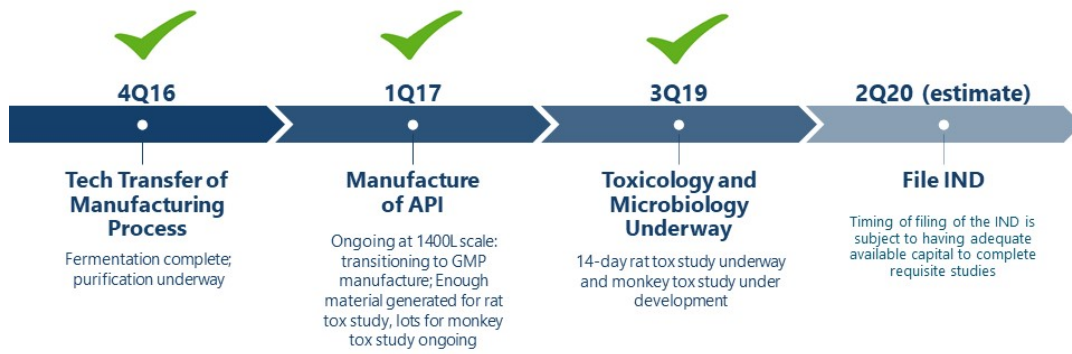


Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

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



Lantibiotics: OG716 *C. difficile* Program Milestones





Corporate Status Update

Capitalization

	Common Stock Equivalents*	Significant Shareholders***	Number Of Shares Beneficially Owned	Percentage Ownership
Common Stock Outstanding	46,124,803	CVI Investments, Inc.	4,000,000	8.70%
Series A Convertible Preferred (As Converted)	941,701	Anson Funds Management LP	4,000,000	8.70%
Series B Convertible Preferred (As Converted)	1,320,002	Intracoastal Capital LLC	3,858,977	7.80%
Series C Non-Convertible Perpetual Preferred** (113,941 shares outstanding)	-	Koski Family Limited Partnership	2,580,365	5.50%
Warrants (WAEP \$1.08)	26,538,593	Intrexon	1,548,165	3.40%
Reserved for issuance under stock incentive plan	8,009,250	Cash*	\$25.7M	
Total	82,934,349			

* Information is as of June 30, 2019.

** As of June 30, 2019, the Non-Voting, Non-Convertible Series C Preferred Shares have a stated value of \$33.847 per share and have an accruing dividend of 20% per year. The Series C Preferred Shares resulted from the conversion of approximately \$3.3 million in debt obligations previously owed to Intrexon.

*** Information as reflected in the Company's Proxy Statement dated May 16, 2019.

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

Experienced Management Team

Dr. Alan F. Joslyn

Director, President and Chief Executive Officer

- Assumed CEO position at Oragenics in June 2016
- Held CEO positions at several private biotechnology companies including Sentinella Pharmaceuticals, Edusa Pharmaceuticals and IML Cook Pharma
- Formerly sat 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

