# 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 23, 2016 (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))

#### Item 8.01 Other Events.

On August 23, 2016, Oragenics, Inc. (the "Company") issued a press release announcing selection of a second generation lantibiotic, OG716, for treatment of *Clostridium difficile* and plans to begin Investigational New Drug (IND) enabling studies. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No. Description

99.1 Press Release dated August 23, 2016.

## **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  $23^{rd}$  day of August, 2016.

ORAGENICS, INC. (Registrant)

BY: /s/ Michael Sullivan

Michael Sullivan Chief Financial Officer



#### Oragenics Selects New Lantibiotic for Further Development in Clostridium difficile Infections

TAMPA, FL, August 23, 2016 – Oragenics (NYSE:MKT – OGEN.BC), a leader in the development of new antibiotics against infectious disease and developing effective treatments for oral mucositis, today announced selection of a second generation lantibiotic, OG716, for treatment of *Clostridium difficile* and plans to begin Investigational New Drug (IND) enabling studies.

OG716, a new, orally-active homolog, has exhibited positive results in an animal model for potential treatment of *Clostridium difficile*. Generated from Oragenics' Mutacin 1140 (MU1140) platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. difficile* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. difficile* spores when compared to a vancomycin positive control.

Through its Exclusive Channel Collaboration agreement (ECC) with Intrexon Corporation (NYSE: XON), ongoing research and development activities are focused on the identification of active lantibiotic homologs with favorable efficacy, safety and drug delivery profiles that can be moved forward in a timely, cost efficient and expeditious manner. Future work will include evaluation of a large lantibiotic library against a variety of infections including those related to methicillin resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococci (VRE).

Dr. Alan Joslyn, Chief Executive Officer and President of Oragenics, said, "We are excited about the selection of a new orally-active lead lantibiotic candidate in OG716. As we move forward with pre-clinical studies and plans to file an IND in 2017, we are optimistic OG716 will ultimately become available for treatment of *C. difficile* infections. This is a further demonstration of successful collaborative efforts with Intrexon as we jointly develop this new class of antibiotics and build on our relationship in the field of lantibiotics and infectious disease control. We will continue to study former lead candidate, OG253, and similar analogs in other infectious disease models."

Philip Gioia, Chief Commercial Officer of Intrexon's Health Sector, commented, "Lantibiotics such as OG716 have potential to play an important role in the fight against bacterial antibiotic resistance. We are excited that our collaboration under the ECC with Oragenics has led to the acceptance of an improved candidate for the treatment of *C. difficile* infections, and we look forward to continuing our joint research programs to identify new analogs to treat other multidrug resistant infections."

#### About Oragenics, Inc.

We are focused on becoming the world 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, a synthetic biology company. The collaborations allow Oragenics 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 Oragenics, 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, 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.

#### For more information contact:

**Oragenics** 

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