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 30, 2016
(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))

Item 8.01 Other Events.

On August 30, 2016, Oragenics, Inc. (the "Company") issued a press release announcing that it has received feedback from the U.S. Food and Drug Administration ("FDA") in response to the Company's request for a Type C meeting, concerning Phase 2 study protocols for the Company's OM therapeutic candidate, AG013. 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 30, 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 30th day of August, 2016.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Receives Supportive FDA Feedback For Initiating A Phase 2 Study Protocol For Oral Mucositis Treatment

TAMPA, FL, August 30, 2016 –Oragenics (NYSE:MKT – OGEN.BC), a leader in the development of novel antibiotics against infectious disease and developing effective treatments for oral mucositis (OM) today announced that it has received feedback from the U.S. Food and Drug Administration (FDA) in response to the Company's request for a Type C meeting, concerning Phase 2 study protocols for the Company's OM therapeutic candidate, AG013. As part of the clinical protocol for the study, Oragenics expects to file the Investigational New Drug (IND) update in late 2016 and initiate the study with AG013 in the United States and Europe during early 2017.

"We are pleased to have the FDA's thorough feedback on protocol design for our Phase 2 trial and drug product manufacturing requirements for evaluating AG013 for the treatment of oral mucositis," said Alan Joslyn, Oragenics' Chief Executive Officer and President. "This is an important milestone in our effort to potentially provide cancer patients with a new therapy for treatment of oral mucositis."

OM results in a painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus and is one of the most commonly reported adverse events associated with cancer chemotherapy affecting up to 500,000 patients annually. OM has a negative effect on patient well-being and if severe, negatively affects a patient's cancer treatment regimen. At present, no drug is approved to prevent the condition broadly and current therapies are primarily palliative in nature, only addressing symptom relief but not treating the underlying causes of the condition.

"Oral mucositis remains a major unmet need for cancer patients receiving cytotoxic radiation and chemotherapy," said Stephen T. Sonis, DMD, DMSc, Senior Surgeon, Divisions of Oral Medicine, Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Dr. Sonis continued, "As suggested by the results of pre-clinical and clinical studies, AG013 may provide a unique delivery platform for an effective intervention. I'm excited that its development program has completed this important first step in moving forward."

Through the genetic engineering of a food grade microbe, *Lactococcus lactis* (*L. lactis*), by the Actobiotics Division of Intrexon Corporation (NYSE: XON), *in situ* production and secretion of peptide therapeutics has been developed, including AG013, an oral rinsing solution designed to deliver human Trefoil Factor 1 (hTFF1) to protect and regenerate damaged mucosal lining of the oral cavity. Under an Exclusive Channel Collaboration Agreement with Intrexon, Oragenics has an exclusive worldwide license to develop and commercialize AG013 to treat oral mucositis in cancer patients.

A Phase 1B clinical trial with AG013 in 25 head and neck cancer patients at high risk for OM demonstrated that AG013 was safe and well tolerated. Data published in the journal *Cancer* showed a 35% reduction in the duration of ulcerative OM in AG013-treated patients vs placebo treated patients. Additionally over 30% of patients treated with AG013 were complete responders, defined as patients who did not develop OM, while all patients receiving placebo developed OM. A Phase 1 pharmacokinetic study in 10 healthy volunteers showed that live AG013 *L. lactis* adhered to the entire oral mucosal surface up to 24 hours after administration of the rinse.

AG013 has already been granted Orphan Drug status in the European Union and applications for Biologic License Application exclusivity and Fast Track designation with the FDA will be filed in the coming months.

About the Study Design

The Phase 2 double blind placebo controlled trial has been designed to evaluate the efficacy, safety, and tolerability of AG013 in patients being treated with standard regimens of concomitant chemoradiation therapy for common cancers of the head and neck. Not only is severe mucositis among the most common complications of treatment in this population, but its impact on patients' ability to tolerate cancer therapy and risk of adverse health and resource use outcomes are frequent and devastating. Oragenics expects to announce additional information about the study design and timelines for the study once they are finalized.

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 FDA's approval of 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 and the allocation of such resources among our product candidates: 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.

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