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 17, 2018
(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)

(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))

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 8.01 Other Events.

Oragenics Announces Receipt of Clearance to Enroll Patients in Phase 2 Clinical Trial in Belgium

On October 17, 2018, Oragenics, Inc. (the "Company") announced it had received clearance to enroll patients in Belgium for its Phase 2 clinical trial of AG013 for the treatment of Oral Mucositis.

A copy of the press release announcing these events is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated October 17, 2018.

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 17h day of October, 2018.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

ORAGENICS, INC. RECEIVES CLEARANCE TO ENROLL PATIENTS IN BELGIUM INTO ITS PHASE 2 CLINICAL TRIAL OF AG013 FOR ORAL MUCOSITIS

TAMPA, Fla., October 17, 2018 — 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 has received clearance to enroll patients residing in Belgium from the Belgian Health Authority, The Federal Agency for Medicines and Health Products (FAMHP), into its Phase 2 clinical trial of AG013, a *live* biotherapeutic product for the potential prevention and treatment of OM.

"Enrolling patients outside of the United States provides an expansive patient base from which to draw for our trial of AG013, allowing us to more rapidly reach our goal of enrolling between 160-180 evaluable patients," stated Alan Joslyn, Ph.D., president and CEO of Oragenics, Inc. "The combination of the expanded number of clinical sites in the United States and Europe along with recent warrant exercises generating proceeds of approximately $9.5 million, should enhance our ability to complete the clinical study in 2019."

The ongoing Phase 2 trial is a double-blind, placebo-controlled, two-arm, multi-center trial, in which approximately 200 patients will be randomized in a 1:1 ratio to receive either AG013 or placebo. The purpose of the study (NCT03234465) is to evaluate the safety, tolerability and efficacy of topically administered AG013 compared to placebo for reducing the incidence and severity of OM in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. Key measures include duration, time to development, and overall incidence of OM (using a World Health Organization scale) during the active treatment phase, which begins from the start of chemoradiation therapy and ends two weeks following its completion.

AG013, which has been granted Fast Track designation with the U.S. Food and Drug Administration and orphan drug status in Europe, is an Intrexon Actobiotics therapeutic candidate formulated to deliver the therapeutic molecule, human 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 these tissues subsequent regeneration. The compound was designed by the company's strategic partner, Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon Corporation (NYSE: XON) whereby Oragenics, Inc. holds an exclusive world-wide license.

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.

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