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: September 23, 2019 (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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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

On September 23, 2019, Oragenics, Inc. ("Oragenics" or the "Company") issued a press release announcing that an abstract on the initial data from the Phase 2 Clinical Trial for AG013 has been accepted for presentation at the European Society for Medical Oncology ("ESMO") Congress 2019 to occur between September 27 and October 1, 2019, in Barcelona, Spain. Copies of the press release and the abstract are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information furnished pursuant to Item 7.01 on this Form 8-K, including Exhibit 99.1 and 99.2 attached hereto, shall not be deemed "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, nor shall it be deemed incorporated by reference into any other filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on September 23, 2019
99.2	Abstract accepted for presentation at the European Society for Medical Oncology Congress

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 23rd day of September, 2019.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

ORAGENICS, INC. TO PRESENT INTERIM DATA ON AG013 AT THE EUROPEAN SOCIETY OF MEDICAL ONCOLOGY CONGRESS

TAMPA, Fla., September 23, 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 announces that an abstract from its ongoing double-blind, randomized, placebo-controlled Phase 2 trial of AG013 in severe oral mucositis, will be presented as a poster at the upcoming European Society of Medical Oncology Congress ("ESMO") on September 27 – October 1, 2019 in Barcelona, Spain,.

The abstract, titled "Severe Oral Mucositis Mitigation by Genetically Modified*Lactococcus Lactis* Bacteria (LLB) Producing Human Trefoil Factor 1 (hTFF1; AG013) In Patients Being Treated with Concomitant Chemoradiation (CRT) for Oral and Oralpharyngeal Cancers (OCOCPC)" can be viewed at www.oragenics.com and will be presented at the ESMO Congress on September 30, 2019.

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 allow 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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SEVERE ORAL MUCOSITIS (SOM) MITIGATION BY GENETICALLY MODIFIED *LACTOCOCCUS LACTIS* BACTERIA (LLB) PRODUCING HUMAN TREFOIL FACTOR 1 (hTFF1; AG013) IN PATIENTS BEING TREATED WITH CONCOMITANT CHEMORADIATION (CRT) FOR ORAL AND OROPHARYNGEAL CANCERS (OCOPC)

Suraj Singh[1], Sandra Nuyts[2], Robert Doline[3], Suma Satti[4], Matthew Schwartz[5], Stephen Thatcher[6], Yuhchyau Chen[7], Sanford Katz[8], James Wade[9], Madhur Garg[10], Jill Wagemans[11], Pol Specenier[12], Claus Wittekindt[13], Lip Lee[14], John Riefler[15], Stephen Sonis[16], Michael Emanuel[17], Fiona Cilli[17], Alan Joslyn[17]

1 MultiCare Health System, Tacoma, WA, USA
2 University Hospital Leuven, Leuven, Belgium
3 CaroMont Health System, Gastonia, NC, USA
4 Ochsner Medical Center, New Orleans, LA, USA
5 Comprehensive Cancer Centers of Nevada-Henderson, Henderson, NV, USA
6 Cancer Care Northwest, Spokane Valley, WA, USA
7 University of Rochester Medical Center, Rochester, NY, USA
8 Willis-Knighton Cancer Center, Shreveport, LA, USA
9 Decatur Memorial Hospital, Decatur, IL, USA
10 Montifiore Medical Center, Bronx, NY, USA
11 St. Maarten General Hospital, Mechelen, Belgium
12 University Hospital Antwerp, Edegem, Belgium
13 University Hospital Giessen, Giessen, Germany
14 The Christie NHS Foundation Trust, Manchester, UK
15 PSI, Inc., King of Prussia, PA, USA
16 Primary Endpoint Solutions, Watertown, MA, USA
17 Oragenics, Inc., Tampa, FL, USA

BACKGROUND

SOM is a devasting consequence of CRT. hTFF1 is a naturally occurring protein that can protect the mucosa. LLB were genetically modified (GM) to produce hTFF1, formulated as an oral rinse and attenuated SOM in patients receiving chemotherapy. The GM LLB lack all necessary components for survival and multiplication. The objective of this ongoing Phase 2 trial is to assess the safety and efficacy of AG013 as a SOM intervention.

METHODS

This is a double-blind, randomized, placebo-controlled trial recruiting ~200 patients with OCOPC at 48 sites (US and Europe). Patients (PTS) receive cumulative RT (cumRT) between 50 Gy – 72 Gy, 2.0-2.2 Gy QD + QW/Q3W cisplatin. At least two mucosal sites at risk of SOM receive minimal cumRT of 50 Gy. PTS are randomized 1:1 to receive placebo or AG013 [LLB strain sAGX0085 engineered to secrete hTFF1 ($2x10^{11}$ CFU/15 mL tid)] starting on CRT day 1 and continuing 2 weeks post-CRT. Beginning on CRT day 1 and continuing Q2W until resolution, OM is assessed by trained assessors and scores assigned centrally. The primary and secondary efficacy endpoints are SOM duration and incidence (WHO criteria). AEs are described by NCI-CTCv4. A DSMB performed a safety analysis following accrual of the first 24 PTS. Tumor response to CRT is evaluated for1-year post CRT.

RESULTS

71 PTS have been randomized across 48 study sites. Complete OM data are available for 42 PTS for whom blinded evaluation (active and placebo) demonstrated an overall SOM incidence of 52%. SOM was noted at 81 of 547 visits (14.8%). 25 PTS have stopped active treatment; 2 for non-compliance, 5 for AEs, and 18 lost to follow-up or unwilling or unable to conform to the protocol. Unexpected SAEs were noted in 9 PTS. No study drug-associated cases of bacteremia or sepsis were seen. DSMB review after the first 24 PTS concluded that there were no contraindications to study continuance

CONCLUSIONS

Observations based on blinded data suggest that AG013 offers a safe, well-tolerated, and potentially efficacious platform to deliver an effective protein intervention for SOM mitigation.