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 30, 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 Disclosure.

On September 30, 2019, study investigators presented initial data for Oragenics, Inc.'s (the "Company") Phase 2 clinical trial for AG013. The study investigators made a presentation at the European Society for Medical Oncology ("ESMO") Congress 2019 in Barcelona, Spain. In conjunction with the presentation, Oragenics issued a press release highlighting the appearance. Copies of the press release and poster presentation are attached hereto as Exhibit 99.1, and 99.2, respectively, and are incorporated herein by reference. Additionally, the poster 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 poster 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 issued on September 30, 2019.
99.2	Poster presentation offered by study investigators on September 30, 2019 at the European Society for Medical Oncology Congress 2019 in Barcelona, Spain.

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 September, 2019.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Presents Interim Data on The AG013 Phase 2 Clinical Trial at the

European Society for Medical Oncology Congress 2019

TAMPA, Fla.—September 30, 2019 - (BUSINESS WIRE)—Oragenics, Inc. (NYSE American: OGEN) ("Oragenics"), a leader in the development of novel antibiotics against infectious diseases and effective treatments for oral mucositis, today announces initial data from its ongoing Phase 2, placebo-controlled, clinical trial of AG013 in oral mucositis presented in a poster session at the European Society for Medical Oncology (ESMO) Congress 2019 in Barcelona, Spain.

Titled, "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)," was presented at the ESMO Congress 2019 in Barcelona, Spain. The poster can be found under the "Presentations" tab in the "News and Media" section of the Company's website, located at www.oragenics.com.

The poster presentation describes the methods and initial blinded results from the ongoing Phase 2 clinical trial for the Company's lead oral mucositis product candidate, AG013. The ongoing Phase 2 clinical 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 three times daily following meals, beginning on the first day of chemoradiation therapy and continuing through the course of cancer treatment. The purpose of this Phase 2 clinical study, (NCT03234465), is to evaluate the efficacy (preventing the occurrence and shortening the duration of SOM), safety, and tolerability of a convenient topically administered rinse of AG013 compared to a placebo for reducing the incidence and severity of oral mucositis in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. The initial data, submitted in the abstract, reflects the results for 42 of the 71 enrolled and randomized patients across 48 study sites and demonstrates that in the blinded, combined placebo and active treatment groups, there was sufficient evidence of efficacy and safety to continue the study.

Additional data accumulated since poster submission, indicates the blinded efficacy evaluation, which included any patient with SOM after week one of treatment and those receiving a cumulative dose of 55 Gy (week 6 of treatment), demonstrated an overall SOM incidence of 47%, which is lower than would be expected based on historical data in the head and neck cancer population receiving this chemoradiation regimen. The overall rate of SOM was reported in only 13.1 % (110 of 842) of evaluable visits. The overall safety profile is consistent with those adverse events that normally occur in cancer patients receiving chemoradiation therapy. As a reminder, the study remains blinded and individual treatment responses remain to be identified. The lead author for the poster presentation is Suraj Singh, M.D., of the MultiCare Regional Cancer Center in Tacoma, Washington.

Alan Joslyn, President & CEO of Oragenics, Inc. said, "As we recently announced, we are more than 75 percent enrolled in this study, and we continue to be encouraged by both the pace of enrollment and the overall clinical results as reported in this poster presentation. While it remains difficult to comment on efficacy outcomes based on these data, we are pleased with the safety profile we are seeing in the study. Due to the high incidence of SOM in head and neck cancer patients, and the blinded results seen to date, we maintain the belief that this compound will provide a convenient meaningful therapeutic benefit for these patients with limited treatment alternatives and no therapies available for prevention of their oral mucositis."

About Oral Mucositis

Oral mucositis is currently one of the most common and debilitating complications of cancer chemo- and radiation therapy. The condition is caused by the breakdown of the mucosal lining in the oral cavity resulting in the formation of painful mouth ulcers. When these mouth ulcers progress to World Health Organization (WHO) grade 3 and 4,

patients by definition, have their ability to eat (grade 3) and drink (grade 4) impacted resulting in emergency room visits or hospitalization in order to provide pain control and nutritional support. During these periods, patients run the risk of interruption of their chemo- and radiation therapies with the potential risk of negative cancer treatment outcomes. The incidence of SOM is approximately 70% in oropharyngeal cancer patients.

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 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.

Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, as amended, that involve significant risks and uncertainties about Oragenics, including but not limited to statements with respect to the use of proceeds of the underwritten offering of common stock and warrants. Oragenics may use words such as "expect," "anticipate," "project," "intend," "plan," "aim," "believe," "seek," "estimate," "can," "focus," "will," and "may" and similar expressions to identify such forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are risks relating to, among other things, market and other conditions, Oragenics's business and financial condition, the timing of future clinical trials; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the Company and the impact of general economic, industry or political conditions in the United States or internationally. Oragenics may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to meet business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Oragenics intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. For additional disclosure regarding these and other risks faced by Oragenics, see disclosures contained in Oragenics's public filings with the SEC, including the "Risk Factors" in the company's Annual Report on Form 10-K, and Quarterly Reports on Form 10-Q. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. The forward-looking statements are made as of the date hereof, and Oragenics undertakes no obligation to update such statements as a result of new information, except as required by law.

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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]

ORAGENICS

ABSTRACT

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 +/- QWI/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 (2x1011 CFU/15 mL bid)] 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 for 1-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.

METHODS

Primary efficacy endpoint

Duration (in days) of severe OM (WHO grades 3 (unable to eat) & 4 (unable to drink))

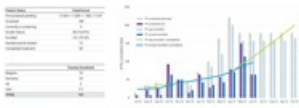
Sample size consideration

190 evaluable patients (80 group) provides 80% power to detect 5-day difference between groups with respect to severe OM

OM secondary endpoints

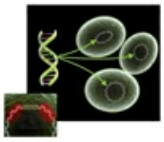
Number of OM free (WHO grades 1 & 2) days, time to onset, use of pain medication, alteration in cancer regimens, emergency room visits for SOM

UPDATED GLOBAL ENROLMENT STATUS



BACKGROUND

- Severe oral mucositis (SOM) is a common, debilitating, treatment-disruptive, and costly side effect of concomitant chemoradiation regimens (CRT) used for the treatment of head and neck cancers.
- There is no approved intervention for the prevention and/or treatment of CRT-related SOM.
- Human trefoil factor (hTFF) is a naturally occurring protein which protects the gastrointestinal mucosa from chemotherapy- and radiotherapy-induced injury (Beck PL et al. Gastroenterology 2004; 126:796-808).
- AG013 provides a topically applied formulation in which genetically modified non-pathogenic bacteria (Lactococcus lactis) is programmed to produce therapeutic levels of hTFF1 to mucosal tissues.
- Results of a Phase 1b clinical trial of AG013 in patients receiving stomatotoxic chemotherapy-based induction therapy demonstrated a reduction in mucositis duration and use of mucositis-related health resources (Limaye SA et al. Cancer 2013; 119:4268-76).
- Objective: The objective of this ongoing Phase 2 trial is to assess the safety and efficacy of AG013 in mitigating severe oral mucositis in patients receiving concomitant chemoradiation for the treatment of oral and oropharyngeal cancers.

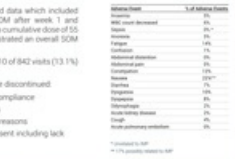


GENETICALLY MODIFIED BACTERIAL SYSTEM

- Convenient, flavored oral rinsing solution composed of genetically modified Lactococcus lactis (non-pathologic food grade bacterium) engineered to deliver mucosal protectant human Trefoil Factor 1 (hTFF1) to mucosal tissues
- Trefoil Factors (TFFs) are a class of peptides involved in protecting mucosal tissues against damage and in subsequent repair
- Cost effective (low COGs) rinse provides daily continuous oropharyngeal coverage with L. lactis producing hTFF1 during entire cancer treatment regimen

EFFICACY AND DISCONTINUATIONS

- Evaluation of blinded data which included any patient with SOM after week 1 and those who received a cumulative dose of 55 Gy (week 6) demonstrated an overall SOM incidence of 47%
- SOM was noted in 110 of 842 visits (13.1%) evaluable visits
- 41 of 151 (27%) have discontinued:
  - 6: protocol non-compliance
  - 7: adverse events
  - 5: administrative reasons
  - 23: withdrew consent including lack of efficacy



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.

CLINICAL STUDY SITES

REFERENCES:

1. Beck PL et al. Chemotherapy- and radiotherapy-induced intestinal damage is regulated by intestinal trefoil factor. Gastroenterology 2004; 126: 796-808.
2. Limaye SA, et al. Phase 1b, multicenter, single-blinded, placebo-controlled, sequential dose escalation study to assess the safety and tolerability of topically applied AG013 in subjects with locally advanced head and neck cancer receiving induction chemotherapy. Cancer 2013; 119: 4268-76.