
**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: July 9, 2020
(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)

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 1.02 TERMINATION OF A MATERIAL DEFINITIVE AGREEMENT

On July 9, 2020, Oragenics, Inc. (the Company” or “Oragenics”) notified Precigen ActoBio Inc. and Intrexon Actobiotics, NV that it was voluntarily terminating the Oral Mucositis Exclusive Channel Collaboration Agreement (the “ECC”) between Oragenics, Inc. and Precigen ActoBio, Inc. (as successor in interest to Intrexon Corporation) and Intrexon Actobiotics NV, dated June 9, 2015, as amended and assigned to ActoBio Therapeutics (collectively “Precigen”). The Company and Precigen mutually agreed to terminate the ECC on July 9, 2020.

The Company entered into the ECC on June 9, 2015, through which the Company commenced its research and development of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus. The Company previously announced top-line data results for the international multicenter Phase 2 clinical trial for AG013 that indicated the primary endpoint and key secondary endpoints demonstrated equivocal results with respect to statistical differences between AG013 and placebo. After further review, the Company assessed the continued pursuit of AG013 in light of such non-efficacious results, including additional underlying data and other factors, and based on such items, determined to no longer pursue the development of AG013 and to terminate the ECC.

In connection with such mutual termination, the Company will comply with applicable regulatory obligations surrounding the discontinued clinical trial and withdrawal of the IND for AG013, as well as the transfer of clinical trial data to Precigen, pay Precigen approximately \$150,000 associated with certain outstanding invoices to Precigen but otherwise will not incur any termination penalties associated with the termination.

Item 8.01. OTHER EVENTS.

On July 10, 2020 the Company issued a press release regarding the termination of the ECC. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and the contents of the press release are hereby incorporated herein by reference.

Item 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	<u>Press Release announcing termination of ECC.</u>

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 10th day of July, 2020.

ORAGENICS, INC.
(Registrant)

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

Oragenics Provides Update on SARS-CoV-2 (COVID-19) Program***Terminates AG013 Oral Mucositis Development Program***

TAMPA (July 10, 2020) — Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or “the Company”) today provided an update on progress with its SARS-CoV-2 (COVID-19) vaccine candidate and announced the termination of its clinical development program with AG013 for the treatment of severe oral mucositis in cancer patients.

While working with Aragen Bioscience, a leading contract research organization focused on accelerating preclinical biologics product development to advance the Company’s recently acquired COVID-19 vaccine candidate, TerraCoV2, the National Institutes of Health-created stabilized pre-fusion spike protein gene has been successfully inserted into Chinese Hamster Cells (“CHO”) and “mini-pool” production and analytical development are underway. The transfer to full-scale manufacture is expected to commence later this summer.

Separately, following a further review of new data and other factors related to the Company’s international multicenter Phase 2 clinical trial of AG013 in oral mucositis, Oragenics has determined to cease further development of AG013 in this indication by discontinuing the trial and withdrawing the applicable Investigational New Drug application. As a result, on July 9, 2020, the Company, Precigen, Inc. (“Precigen”) and Precigen’s wholly owned subsidiary mutually agreed to terminate the Exclusive Channel Collaboration (“ECC”) agreement for AG013 as a treatment of severe oral mucositis in cancer patients. The Company expects to continue to comply with any applicable regulatory requirements with respect to discontinuing the clinical trial.

“As we await Biomedical Advanced Research and Development Authority (“BARDA”) and other federal and state non-dilutive grant decisions, we expect to use our available cash to continue development of TerraCoV2, with the goal of bringing this COVID-19 vaccine candidate into human clinical trials by early 2021,” said Alan Joslyn, Ph.D., President and CEO of Oragenics. “Although the Phase 2 AG013 clinical trial demonstrated activity in certain patient populations, the overall lack of efficacy along with other factors, inclusive of strategic product portfolio considerations, led us to the decision to discontinue further development of AG013 under the ECC.”

About Oragenics, Inc.

Oragenics, Inc. is focused on developing the TerraCoV2 immunization product candidate to combat the novel coronavirus pandemic and the further development of effective treatments for novel antibiotics against infectious disease. Through its wholly owned subsidiary Noachis Terra, the Company is dedicated to the development and commercialization of a vaccine candidate providing specific immunity from the novel coronavirus, SARS-CoV-2, which causes COVID-19. The TerraCoV2 immunization leverages coronavirus spike protein research conducted by the National Institutes of Health, which issued a worldwide, nonexclusive intellectual property license to Noachis Terra. In addition, Oragenics has an exclusive worldwide channel collaboration with ILH Holdings, Inc. relating to the development of novel antibiotics.

For more information about Oragenics, please visit www.rogenics.com.

Safe Harbor Statement

Under the Private Securities Litigation Reform Act of 1995: This press 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, assumptions and currently available information. 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, except as required by law.

CONTACTS:

Oragenics, Inc.
Michael Sullivan
Chief Financial Officer
813-286-7900
msullivan@rogenics.com

or

Investors:

John Marco
Managing Director
CORE IR
516-222-2560
johnm@coreir.com

Media:

Jules Abraham
CORE IR
917-885-7378
julesa@coreir.com

###
