
**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: April 15, 2020
(Date of earliest event reported)

Orogenics, 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:

Title of each class
Common Stock

Trading Symbol(s)
OGEN

Name of each exchange on which registered
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 8.01 Other Events.

Orogenics Announces Results of Top-Line Data Related to its Phase 2 Clinical Trial.

On April 15, 2020, Orogenics, Inc. (the “Company”) announced the results of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013.

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.

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release issued on April 15, 2020.
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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 15th day of April, 2020.

ORAGENICS, INC. (Registrant)

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

Oragenics, Inc. Announces Early Top-Line Results of Phase 2 Clinical Trial of AG013 for Oral Mucositis in Chemoradiation Treatment of Head and Neck Cancer

TAMPA, Fla—April 15, 2020 — **Oragenics, Inc. (NYSE American: OGEN)**, a leader in the development of new antibiotics against infectious diseases and effective treatments for oral mucositis, announced today that early top-line results of the company’s Phase 2 clinical trial of AG013 in oral mucositis in chemoradiation in head and neck cancer patients did not demonstrate statistical significance on the primary endpoint of severe oral mucositis duration when compared to placebo. AG013 was found to be safe based on review of topline adverse event information.

Alan Joslyn, Ph.D., president and CEO of Oragenics stated, “We have now received the first cut of top line results for the study of AG013 in the prevention of oral mucositis in chemoradiation treatment of head and neck cancer. The results are equivocal in relation to the efficacy outcomes and we now await a more detailed ongoing analyses to determine if there may be potential efficacy for sub-patient populations, which we expect over the coming weeks.”

About Oragenics, Inc.

Oragenics, Inc. is focused on becoming a leader in novel antibiotics against infectious disease and on developing effective treatments for oral mucositis. Oragenics has an exclusive worldwide channel collaboration with ActoBio, a wholly-owned subsidiary of Precigen, Inc. The collaboration allows Oragenics to accelerate the development of microbe-based biotherapeutics for oral mucositis. Oragenics also has a collaboration with ILH Holdings, Inc. focused on the development of a novel class of antibiotics.

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.

Oragenics, Inc.

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