

ZOGENIX, INC.

Form 8-K

February 12, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 6, 2019

ZOGENIX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware 001-34962 20-5300780
(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) Identification No.)

5858 Horton Street, Suite 455, Emeryville, CA 94608
(Address of Principal Executive Offices) (Zip Code)
Registrant's telephone number, including area code: (510) 550-8300
(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 1.01 Entry into a Material Definitive Agreement.

On February 6, 2019, Zogenix International Limited, a wholly-owned subsidiary of Zogenix, Inc. (collectively, the “Company”) entered into a Master Supply Agreement (the “Agreement”) with Aptuit (Oxford) Limited, an Evotec company (“Aptuit”), pursuant to which Aptuit will be the commercial manufacturer and supplier of the fenfluramine active pharmaceutical ingredient (“API”) used in the Company’s product candidate FINTEPLA®. The Agreement is effective as of January 31, 2019 (the “Effective Date”).

Pursuant to the Agreement, Aptuit will provide the Company with the API for a specified price, which price may be adjusted, subject to specified limitations. Aptuit has been providing the API to the Company for several years for the Company’s clinical trial material supply needs and registration batches. Under the Agreement, the API will be supplied pursuant to purchase orders which the Company may deliver to Aptuit from time to time. At least 30 days before the anticipated approval of FINTEPLA by a regulatory agency, and then each month following approval, the Company is required to deliver a 24-month forecast of its expected commercial orders, a portion of which will be considered a binding, firm order.

The term of the Agreement is five years from the Effective Date, which term shall be automatically extended for successive two year periods thereafter, unless terminated earlier. Either party may terminate the Agreement (1) upon specified written notice to the other party, subject to advance notice periods of at least 12 months, if terminated by the Company, and at least 24 months, if terminated by Aptuit, (2) upon written notice if the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under the Agreement within a specified period following receipt of written notice of such breach, and (3) immediately upon written notice to the other party in the event that the other party files for bankruptcy, reorganization, liquidation or receivership proceedings, or a substantial portion of the assets of such party is assigned for the benefit of such party’s creditors. The Agreement will also terminate automatically if FINTEPLA is withdrawn as a result of regulatory review or the Company decides to cease development activities of FINTEPLA.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ending March 31, 2019. The Company intends to seek confidential treatment for certain portions of the Agreement.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZOGENIX, INC.

Date: February 12, 2019 By: /s/ Michael P. Smith
Name: Michael P. Smith
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary