ZOGENIX, INC.
Form 8-K
March 19, 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): March 18, 2019

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

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

5959 Horton Street, Suite 500, Emeryville, CA	94608
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (510) 550-8300
5858 Horton Street, Suite 455
Emeryville, CA 94608
(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 March 18, 2019, Zogenix, Inc. (the "Company") entered into a Distributorship Agreement (the "Agreement") with Nippon Shinyaku Company, Ltd. ("Shinyaku"), pursuant to which Shinyaku will act as the exclusive distributor for the promotion, marketing, sale and distribution of the Company's product candidate FINTEPLA (the "Product") in Japan (the "Territory"). The Company will retain responsibility for completing its global clinical development programs for the Product, including those already underway, to support the Company's planned submissions of new drug applications in Japan for the treatment of Dravet syndrome and Lennox-Gastaut syndrome.

Pursuant to the Agreement, Shinyaku has agreed to pay the Company $20 million, a major portion of which will be paid in connection with signing and the remainder of which will be paid over the next two years. The Company can earn up to $66.0 million from Shinyaku for the achievement of certain regulatory milestones relating to the treatment of Dravet syndrome and the treatment of Lennox-Gastaut syndrome. Additionally, the Company can earn up to $42.5 million for the achievement of certain net sales milestones by Shinyaku. Shinyaku will also pay the Company in each fiscal year a tiered transfer price for the Product in proportion to the manufacturing cost per unit of the Product, the net sales for such fiscal year, and a certain markup percent of the applicable aggregate net price of the Product for such fiscal year. The Product transfer price will be between a mid-twenties percentage and capped at a low-thirties percentage of the aggregate annual net sales of the Product in the Territory for the applicable fiscal year.

The Agreement expires on September 1, 2045, unless earlier terminated by either party. The Agreement may be terminated by either party (1) with one year prior written notice to the other party on or after the date of the first commercial sale of a competing generic version of the Product within the Territory, (2) for a material breach of the other party, following expiration of the applicable notice and cure periods under the Agreement, (3) upon written notice to the other party following the bankruptcy, dissolution, or winding up of such other party, (4) if, prior to the launch of the Product in the Territory, a party has a good faith concern, based on credible evidence, that such launch is not likely to be possible with commercially reasonable efforts, (5) upon thirty business days written notice in the event that the other party undergoes a change in control, or (6) if a party believes that the Product poses a substantial safety concern. The Company may also terminate the Agreement following the second anniversary of the first commercial sale of the Product in the Territory if Shinyaku has failed to achieve or maintain certain diligence obligations under the Agreement. Shinyaku may also terminate the agreement if, prior to the launch of the Product in the Territory, Shinyaku has a good faith concern that the Product will not be commercially viable in the Territory.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2019. The Company plans to request confidential treatment for certain portions of the Agreement.

Safe Harbor Statement

The Company cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potent "suggests," "assuming," "designed," and similar expressions are intended to identify forward-looking statements. These statements include the timing and amount of the portion of the $20 million payment that was not received upon signing the exclusive distribution agreement with Shinyaku, the achievement of regulatory or sales-based milestones by Nippon Shinyaku, the Company's plans regarding the development of FINTEPLA in Dravet syndrome and LGS, and the timing and results of the ongoing clinical trials in Japan. These statements are based on the Company's current beliefs and expectations. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the ongoing clinical trials of FINTEPLA in Japan may fail to reach their primary endpoints; even if the clinical trials are successfully, the Japanese regulatory agency may require additional clinical trials or analyses prior to a regulatory

submission for the approval of FINTEPLA in Japan; the credit risk that Shinyaku fails to pay the remainder of the $20 million initial payment; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; and other risks described in the Company's filings with the U.S. Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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: March 19, 2019

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