ZOGENIX, INC.
Form 8-K
May 02, 2012

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): May 2, 2012

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.)**

12400 High Bluff Drive, Suite 650,

San Diego, CA **92130**
(Address of Principal Executive Offices) **(Zip Code)**
Registrant s telephone number, including area code: (858) 259-1165

(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 (*see* General Instruction A.2. below):

¨ 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))

Item 8.01 Other Events.

On May 2, 2012, Zogenix, Inc. (the Company) submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for Zohydro (hydrocodone bitartrate extended-release capsules), the Company s lead investigational product candidate for the treatment of chronic pain. The Company has included in the NDA a Risk Evaluation and Mitigation Strategy (REMS), which is intended to control inappropriate prescribing, misuse and abuse of extended-release opioids while maintaining patient access to essential pain medications.

The NDA submission is based on data from over 1,100 patients with chronic pain participating in the Company s pivotal Phase 3 efficacy study (Study 801) and an open-label Phase 3 safety study (Study 802) of Zohydro. In conjunction with the NDA submission, the Company is required to make a milestone payment of $1.0 million to Alkermes Pharma Ireland Limited (APIL), a subsidiary of Alkermes, plc, under the Company s exclusive license agreement with APIL in the United States for Zohydro.

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: May 2, 2012

By: /s/ Ann D. Rhoads
Name: Ann D. Rhoads
Title: Executive Vice President, Chief Financial Officer,

Treasurer and Secretary