ZOGENIX, INC.
Form 8-K
August 17, 2011

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): August 17, 2011

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.)**

12671 High Bluff Drive, Suite 200, 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 August 17, 2011, Zogenix, Inc. (the Company or Zogenix) announced positive top-line results from its pivotal Phase 3 efficacy trial (Study 801) of Zohydro (*hydrocodone bitartrate*) extended-release capsules.

The trial successfully met the primary efficacy endpoint of the study in demonstrating that Zohydro resulted in significantly (p=0.008) improved chronic pain relief compared to placebo. The two key secondary endpoints were also met: specifically, the proportion of patients with at least 30% improvement in pain intensity and the improvement of overall satisfaction of medication. Additional study endpoints were supportive of the efficacy of Zohydro compared to placebo. The study demonstrated that Zohydro was generally well tolerated. The most commonly reported adverse events in patients treated with Zohydro (>5%) were constipation, nausea and urinary tract infection.

The multi-center randomized, double-blind, placebo-controlled study enrolled opioid-experienced patients aged 18-75 who had an established clinical diagnosis of moderate to severe chronic lower back pain and inadequate pain relief from their existing therapy. The trial consisted of an open-label conversion and titration phase of Zohydro followed by a 12-week placebo-controlled treatment phase comparing Zohydro 20-100 mg every 12 hours to placebo. More than 300 patients were randomized into the double-blind treatment phase.

The primary objective of this study was to evaluate the relative efficacy of Zohydro as measured by the change from baseline to the end of treatment in pain intensity. The protocol specified primary endpoint was the mean change from baseline to the end of 12 weeks of treatment in the average 24-hour pain intensity ratings based on the 0-10 Numerical Rating Scale from daily electronic diaries comparing Zohydro and placebo.

The Company plans to submit a new drug application (an NDA) for Zohydro to the U.S. Food and Drug Administration (the FDA) by early 2012. Study 801 is part of the ongoing Phase 3 program for Zohydro. An additional open-label safety study is ongoing in patients with moderate to severe chronic pain (Study 802). This long-term safety study required by the FDA to support an NDA filing is anticipated to be completed in the third quarter of 2011.

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Zogenix 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, potential, suggests, assuming, designed and similar ex to identify forward-looking statements. These statements are based on the company s current beliefs and expectations. These forward-looking statements include statements regarding: the potential for, and timing of, an NDA submission for Zohydro and the timing of the completion of Study 802 for Zohydro. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this presentation due to the risk and uncertainties inherent in Zogenix s business, including, without limitation: the top-line data Zogenix has reported for Zohydro is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial, and may also change in connection with the continued review of such data as part of Zogenix s planned submission and the FDA s review of the NDA for Zohydro; the progress and timing of Study 802 and additional single-dose pharmacokinetic and clinical pharmacology trials and pre-clinical studies required for submission of an NDA for Zohydro and approval of this product candidate; the potential that earlier clinical trials may not be predictive of future results; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; the impact of any inability to raise sufficient capital to fund ongoing operations; the ability of Zogenix and its licensors to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its products and product candidates and the ability to operate its business without infringing the intellectual property rights of others; and other

risks described in Zogenix s filings with the 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 Zogenix 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: August 17, 2011

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

Treasurer and Secretary