

ZOGENIX, INC.
Form 8-K
April 15, 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): April 13, 2011

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-34962
(Commission

File Number)

20-5300780
(IRS Employer

Identification No.)

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12671 High Bluff Drive, Suite 200, San Diego, CA
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (858) 259-1165

92130
(Zip 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 (*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 April 13, 2011, Zogenix, Inc. (the Company or Zogenix), at the 63rd Annual Meeting of the American Academy of Neurology in Honolulu, Hawaii, presented clinical data from its Phase 4 open-label, multicenter study of SUMAVEL[®] DosePro[®] (sumatriptan injection) Needle-free Delivery System.

The study evaluated treatment Overall Satisfaction, treatment confidence, patient preference, and treatment tolerability for Sumavel DosePro in adult patients diagnosed with migraine and currently treated with triptans.

Treatment satisfaction was measured using the validated Patient Perception of Migraine Questionnaire, Revised (the PPMQ-R). Among over 200 current triptan users (any drug or dosage form) self-administering Sumavel DosePro to treat multiple migraine attacks, PPMQ-R Overall Satisfaction increased significantly ($p=0.0007$) from baseline to the end of treatment. The results also demonstrated a significant improvement ($p<0.0001$) in the PPMQ-R Total score, which is a composite of subscale scores for 17 questions relating to efficacy, functionality, and ease of use. Patients reported enhanced confidence in treating repeated migraine attacks after trying Sumavel DosePro.

The study also reported on the efficacy and tolerability of Sumavel DosePro among current triptan users over multiple migraine attacks. The results confirmed that Sumavel DosePro is safe and well tolerated by migraine patients, and demonstrated that it provided rapid, sustained relief from migraine pain, as well as associated symptoms such as nausea, photophobia, and phonophobia. Using Sumavel DosePro, one-third of the 669 treated migraine episodes had pain relieved in 15 minutes, with 70% achieving pain relief within 30 minutes. Pain freedom was achieved in 61% of the treated attacks within two hours. These incidences of pain relief and pain-free response for needle-free Sumavel DosePro are consistent with those demonstrated by previous double-blind, placebo-controlled clinical studies of injectable sumatriptan.

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 expressions 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 attributes of Sumavel DosePro. 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 report due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the market potential for migraine treatments, and Zogenix's ability to compete within that market; inadequate therapeutic efficacy or unexpected adverse side effects relating to Sumavel DosePro that could delay or prevent commercialization, or that could result in recalls or product liability claims; Zogenix's dependence on its collaboration with Astellas Pharma US, Inc. to promote Sumavel DosePro; and other risks described in the Company's prior press releases and 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: April 15, 2011

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

Treasurer and Secretary