POZEN INC /NC

FORM 8-K
(Current report filing)

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Address	1414 RALEIGH ROAD SUITE 400 CHAPEL HILL, NC 27517
Telephone	919-913-1030
CIK	0001059790
SIC Code	2834 - Pharmaceutical Preparations
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Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 23, 2012

POZEN INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-31719**	**62-1657552**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1414 Raleigh Road, Suite 400 **Chapel Hill, North Carolina** **(Address of Principal Executive Offices)**	**27517** **(Zip Code)**

(919) 913-1030
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

¨ 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.

During a pre-submission meeting with respect to its New Drug Application ("NDA") for PA32540, which contains 325 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet, the United States Food & Drug Administration (the "FDA") suggested that POZEN Inc. (the "Company") also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for PA32540. Absent the availability of such a lower dose formulation in the market if PA32540 is approved, the FDA indicated that it may limit the indication for PA32540 to use in post coronary artery bypass graft surgery (CABG) with a treatment duration not to exceed one year. The Company believes that the FDA is concerned that, without a formulation containing a lower dose of aspirin, physicians will not have a full range of dosing options available to prescribe in accordance with current cardiovascular treatment guidelines, which recommend doses of 81 mgs or 162 mgs of aspirin for most indications. The Company intended to seek an indication for the secondary prevention of cardiovascular disease in patients at risk for gastric ulcers.

The Company has generated clinical pharmacology data and chemical, manufacturing and controls (CMC) data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet (PA8140). The Company intends to file this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin as part of its NDA for PA32540. At this time, the Company does not intend to conduct Phase 3 clinical trials for PA8140. The Company anticipates that the data package submitted for PA8140 will be similar to that used to gain approval for a lower dosage formulation of VIMOVO™ (naproxen/esomeprazole magnesium) containing 375 mg of naproxen.

Generation of additional data with respect to PA8140 and incorporation of data into the NDA for PA32540 may delay submission of the NDA for approximately 6 months from the original planned submission date in the third quarter of 2012, but the exact timing of the NDA submission has not yet been determined. The Company is also assessing what additional development activities with respect to PA8140 will be required and the costs thereof.

The Company has no guarantee such data will be sufficient for the FDA to approve PA8140 or to allow a broader indication for PA32540. The FDA will make a final determination with respect to the approvability of and indications for PA32540 and PA8140 during the review of the Company's NDA for the products.

The Company intends to further discuss the subject matter of this Form 8-K during a webcast to present its first quarter 2012 results to be held on Tuesday, May 1, 2012 at 11:00 am (ET). The webcast will be able to be accessed live and will be available later for reply at www.pozen.com.

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.

POZEN Inc.

By: /s/ William L. Hodges
Name: William L. Hodges
Title: Chief Financial Officer

Date: April 26, 2012