

EXELIXIS INC
Form 8-K
August 29, 2012

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): August 29, 2012

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-30235
(Commission

File Number)

04-3257395
(IRS Employer

Identification No.)

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210 East Grand Ave.

South San Francisco, California 94080

(Address of principal executive offices) (Zip Code)

(650) 837-7000

(Registrant's telephone number, including area code)

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 29, 2012, Exelixis, Inc. (the Company) was notified by the Food and Drug Administration (the FDA) that the Company's new drug application (NDA) for cabozantinib as a treatment for patients with progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer has been removed from the agenda for the November 8 and November 9, 2012 meeting of the FDA's Oncologic Drugs Advisory Committee (ODAC). As a result, the Company does not anticipate a discussion of the NDA by ODAC. The previously announced Prescription Drug User Fee Act (PDUFA) action date remains November 29, 2012.

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.

Date: August 29, 2012

EXELIXIS, INC.

/s/ James B. Bucher
Vice President, Corporate Legal Affairs and Secretary