

EXELIXIS INC
Form 8-K
June 08, 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): May 30, 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.)

Edgar Filing: EXELIXIS INC - Form 8-K

210 East Grand Ave.

South San Francisco, California 94080

(Address of principal executive offices, and including 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.

Initiation of Cabozantinib Pivotal Trial in Metastatic Castration-Resistant Prostate Cancer

On May 30, 2012, Exelixis, Inc. (the Company) announced the initiation of COMET-1 (CabOzantinib MET Inhibition CRPC Efficacy Trial-1), the Company's planned phase 3 pivotal trial of cabozantinib in men with metastatic castration-resistant prostate cancer (mCRPC). The primary endpoint for COMET-1 is overall survival in mCRPC patients who have had disease progression after treatment with docetaxel and abiraterone acetate and/or MDV3100. The Company expects data from COMET-1 to be available in the first half of 2014.

Completion of Submission of New Drug Application for Cabozantinib for the Treatment of Medullary Thyroid Cancer

On May 30, 2012, the Company also announced that it had completed the submission of its rolling New Drug Application (NDA) with the United States Food and Drug Administration (the FDA) for cabozantinib as a potential treatment for patients with advanced medullary thyroid cancer. The Company has requested Priority Review designation from the FDA. If such designation is granted, the Company expects that the FDA's review would be completed six months from the date of the FDA's receipt of the final submission.

Forward-Looking Statements

The statements in this Current Report on Form 8-K that the Company expects data from COMET-1 to be available in the first half of 2014, and if the Priority Review of the NDA from the FDA is granted, the Company expects that the FDA's review would be completed six months from the date of the FDA's receipt of the final submission, are forward-looking statements. These forward-looking statements are based upon the Company's current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the Company's ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the risk of unexpected delays in the availability of data at the referenced times; the sufficiency of the Company's capital and other resources; and the uncertainty of the FDA approval process. These and other risk factors are discussed under Risk Factors and elsewhere in the Company's quarterly report on Form 10-Q for the quarter ended March 30, 2012, and the Company's other filings with the Securities and Exchange Commission. The Company expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which such statements are based.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EXELIXIS, INC.

Date: June 8, 2012

/s/ James B. Bucher
James B. Bucher

Vice President, Corporate Legal Affairs and Secretary