

EXELIXIS, INC.
Form 8-K
December 20, 2013

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): December 19, 2013

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-30235
(Commission

File Number)
210 East Grand Ave.

04-3257395
(IRS Employer

Identification No.)

South San Francisco, California 94080

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(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.

On December 19, 2013, Exelixis, Inc. announced that the European Committee for Medicinal Products for Human Use (the CHMP) has issued a positive opinion of the Marketing Authorization Application (MAA) for COMETRIQ® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma. The proposed indication also states that for patients in whom Rearranged during Transfection (RET) mutation status is not known or is negative, a possible lower benefit should be taken into account before individual treatment decisions. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union.

Forward-Looking Statements

The statements in this Current Report on Form 8-K regarding the review by the European Commission of the CHMP's referenced positive opinion and of the referenced MAA for COMETRIQ® (cabozantinib) are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' 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 uncertainty of regulatory approval processes and changes in economic and business conditions. These and other risk factors are discussed under Risk Factors and elsewhere in Exelixis' quarterly report on Form 10-Q for the three months ended September 27, 2013, filed with the Securities and Exchange Commission on October 30, 2013, and Exelixis' other filings with the Securities and Exchange Commission. Exelixis 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 Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any 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: December 20, 2013

/s/ James B. Bucher
James B. Bucher

Vice President, Corporate Legal Affairs and Secretary