EXELIXIS, INC.
Form 8-K
March 25, 2014

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): March 25, 2014

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-30235**	**04-3257395**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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.

On March 25, 2014, Exelixis, Inc. (the Company) announced that the European Commission has approved COMETRIQ® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma. The European Commission granted conditional marketing authorization following a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) issued in December 2013. Similar to another drug approved in this setting, the approved indication 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.

Forward-Looking Statements

The statements in this Current Report on Form 8-K regarding the referenced conditional marketing authorization for COMETRIQ® (cabozantinib) in the European Union are forward-looking statements. Forward-looking statements involve risks and uncertainties. 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 risk that unanticipated developments could delay or prevent the launch, commercialization, manufacturing, distribution and availability of COMETRIQ; the degree of market acceptance of COMETRIQ; the extent to which coverage and reimbursement for COMETRIQ will be available from third-party payors; risks and uncertainties related to the Company s ability to maintain compliance with the requirements for conditional marketing authorization in the European Union; risks and uncertainties related to the Company s compliance with other applicable regulatory requirements, including healthcare fraud and abuse laws and post-marketing requirements; the Company s dependence on third-party vendors; market competition; 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 the Company s annual report on Form 10-K for the fiscal year ended December 27, 2013, filed with the Securities and Exchange Commission (SEC) on February 20, 2014, and the Company s other filings with the SEC. 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 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: March 25, 2014

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