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): November 29, 2012

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-30235**	**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) (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.

FDA Approval of COMETRIQ™ (cabozantinib) Capsules for Treatment of Progressive Metastatic Medullary Thyroid Cancer

On November 29, 2012, Exelixis, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has approved COMETRIQ™ (cabozantinib) for the treatment of progressive, metastatic medullary thyroid cancer in the United States. COMETRIQ is an inhibitor of multiple receptor tyrosine kinases involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment. The COMETRIQ label has boxed warnings concerning risk of perforations and fistulas, and hemorrhage. The recommended dose of COMETRIQ is 140 mg orally, once daily (one 80 mg capsule and three 20 mg capsules). The Company currently expects that COMETRIQ will be commercially available in late January 2013, and the wholesale acquisition cost has been set at $9,900 for a 28-day supply. COMETRIQ has been flat priced, meaning each dosage strength will be priced the same. Exelixis currently estimates that there are between 500 and 700 patients diagnosed annually in the United States with metastatic medullary thyroid cancer eligible for COMETRIQ.

EMA Acceptance of Marketing Authorization Application for COMETRIQ™ (cabozantinib)

On November 29, 2012, the Company announced that the European Medicines Agency ("EMA") has accepted for review the Marketing Authorization Application ("MAA") for COMETRIQ™ (cabozantinib) for the proposed indication of treatment of progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer. The completion of the MAA validation process confirms that the submission is sufficient to permit a substantive review for marketing authorization in the European Union. COMETRIQ previously received orphan drug designation in the European Union from the Committee for Orphan Medicinal Products for the treatment of medullary thyroid cancer.

This current report on Form 8-K contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectations regarding the commercial availability and pricing of COMETRIQ; the number of patients eligible for COMETRIQ; and the referenced review for marketing authorization for COMETRIQ in the European Union. Words such as "expects," "will," "estimates," "eligible," "sufficient," "permit," "review," and similar expressions are intended to identify 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 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 Exelixis' compliance with 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 the regulatory approval process; 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 quarter ended September 28, 2012, filed with the Securities and Exchange Commission ("SEC") on November 7, 2012, and Exelixis' other filings with the SEC. 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.

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: November 30, 2012

EXELIXIS, INC.

/s/ James B. Bucher

Vice President, Corporate Legal Affairs and Secretary