# 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): July 6, 2011**

# 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.**

**Update on Cabozantinib Development Activities**

On July 6, 2011, Exelixis, Inc. (the "Company") announced that it has extended the timing for reporting top-line data from the Company's ongoing phase 3 pivotal trial of cabozantinib in patients with medullary thyroid cancer ("MTC"), known as the EXAM trial, by approximately three months. The timeline is being extended from the middle of this year to provide additional time for the trial to reach the pre-specified number of progression-free survival events required for un-blinding of the data.

The Company also announced on July 6, 2011 that, given the extension of the timing for the un-blinding of the EXAM trial, it now plans to initiate a rolling submission of its new drug application for cabozantinib in MTC (the "NDA") in the fourth quarter 2011 by submitting with the United States Food and Drug Administration (the "FDA") key parts of the NDA, including the preclinical and chemistry, manufacturing and controls ("CMC") information, later in 2011, and expects to complete the NDA file in the first quarter of 2012. Cabozantinib is eligible for a rolling submission as a result of the FDA's granting Fast Track designation for cabozantinib in MTC. Assuming a positive outcome of the EXAM trial, the Company currently anticipates a commercial launch of cabozantinib in MTC in the second half of 2012.

The Company also reported on July 6, 2011 that the protocol for the Company's planned XL184-306 pivotal trial for cabozantinib in castration-resistant prostate cancer ("CRPC") using a combined endpoint of pain reduction and bone scan response was submitted to the FDA in June for consideration of a special protocol assessment. The Company's goal is to initiate this trial by the end of 2011. The Company is also planning two additional pivotal trials in CRPC for overall survival and bone metastasis-free survival (XL184-307 and XL184-308), respectively, and expects to initiate both of these trials in 2012.

**Forward-Looking Statements**

This current report on Form 8-K contains forward-looking statements, including, without limitation, statements related to: the continued development of cabozantinib; the timeline for the ongoing phase 3 pivotal trial of cabozantinib in MTC, including the timing for reporting top-line data, the timing for submitting an NDA and the anticipated timing for the commercial launch of cabozantinib in MTC; Exelixis' goal to initiate the first pivotal trial of cabozantinib in CRPC (XL184-306) by the end of 2011; and the planning for two additional pivotal trials in CRPC (XL184-307 and XL184-308) and Exelixis' expectation to initiate these trials in 2012. Words such as "extended," "plans," "expects," "anticipates," "goal," "planning," 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: risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the availability of data at the referenced times; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; timely receipt of potential reimbursements, milestones, royalties and profits under Exelixis' collaborative agreements; Exelixis' ability to enter into new collaborations; market competition; 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 April 1, 2011 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.

**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: July 8, 2011

EXELIXIS, INC.

/s/ James B. Bucher

Vice President, Corporate Legal Affairs and Secretary