EXELIXIS, INC.
Form 8-K
July 20, 2015

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 20, 2015

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) (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 July 20, 2015, Exelixis, Inc. ("Exelixis") announced positive top-line results from the primary analysis of METEOR, Exelixis' phase 3 pivotal trial comparing cabozantinib to everolimus in patients with metastatic renal cell carcinoma ("RCC") who have experienced disease progression following treatment with at least one prior VEGF receptor tyrosine kinase inhibitor. The trial met its primary endpoint of demonstrating a statistically significant increase in progression-free survival ("PFS") for cabozantinib versus everolimus in the first 375 randomized patients as determined by an independent radiology committee. Cabozantinib reduced the risk of disease progression or death by 42 percent compared to the everolimus arm (hazard ratio [HR]=0.58, 95 percent CI 0.45 - 0.75, p<0.0001).

Data pertaining to overall survival ("OS") in the entire study population of 658 patients, a secondary endpoint of the trial, were immature at the data cutoff. A prespecified interim analysis, triggered by the primary analysis for PFS, showed a trend in OS favoring cabozantinib (HR = 0.67, unadjusted 95 percent CI 0.51 - 0.89; p=0.005). At the time of the interim analysis, the pre-specified p-value of 0.0019 to achieve statistical significance was not reached. The trial will continue to the final analysis of OS anticipated in 2016.

METEOR’s primary analysis included a review of serious adverse event ("SAE") data. Based on this analysis the frequency of SAEs of any Grade regardless of causality was approximately balanced between study arms. The rate of treatment discontinuation due to adverse events was low (10%) in both study arms.

Detailed results of the METEOR trial will be submitted for presentation at an upcoming medical conference.

In April 2015, cabozantinib received Fast Track designation by the United States Food and Drug Administration for the potential treatment of advanced RCC patients who have received one prior therapy. Based on the outcome of METEOR, Exelixis plans to complete regulatory filings in the United States and European Union in early 2016.

On July 20, 2015, the Compensation Committee of the Board of Directors of Exelixis convened to determine that top-line efficacy data received from METEOR met its primary endpoint at the level specified and within the time period permitted by the performance goals set by the Compensation Committee for performance-based stock options granted to employees in 2013, 2014 and 2015. As a result of such determination, approximately 7.0 million performance-based stock options granted to Exelixis employees, including executive officers, have vested.

The statements in this Current Report on Form 8-K that the trial will continue to the final analysis of OS anticipated in 2016, that detailed results of the trial will be submitted for presentation at an upcoming medical conference, and that Exelixis plans to complete regulatory filings in the United States and European Union in early 2016, are forward-looking statements. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the clinical, therapeutic and commercial value of cabozantinib; the availability of data at the expected times; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical study; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the general sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; market competition; changes in economic and business conditions; and other factors discussed under the caption “Risk Factors” in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on April 30, 2015 and in Exelixis' other filings with the SEC. The forward-looking statements made in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. 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.

EXELIXIS, INC.

July 20, 2015	/s/ JEFFREY J. HESSEKIEL
Date	Jeffrey J. Hessekiel
	Executive Vice President, General Counsel and Secretary