EXELIXIS, INC.
Form 8-K
December 05, 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): December 1, 2014

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.

On December 1, 2014, Exelixis, Inc. (the "Company") announced top-line results from the final analysis of COMET-2, a randomized, double-blind, controlled trial of cabozantinib in men with metastatic castration-resistant prostate cancer ("mCRPC") who are suffering from moderate to severe pain despite optimized narcotic medication, and whose disease has progressed following treatment with docetaxel as well as abiraterone and/or enzalutamide. The trial did not meet its primary endpoint of alleviation of bone pain, as determined by comparing the percentage of patients in the two treatment arms who achieved a pain response at Week 6 that was confirmed at Week 12 without increase in narcotic medication. Fifteen percent of patients in the cabozantinib arm reported a pain response, compared to 17 percent of patients in the control arm receiving mitoxantrone/ prednisone. The difference in pain response between the arms was not statistically significant. The safety profile of cabozantinib in the trial was consistent with that observed in previous studies in mCRPC.

Following the September 1, 2014 announcement of top-line results for COMET-1, the Company's other phase 3 pivotal trial of cabozantinib in men with mCRPC, the Company deprioritized the cabozantinib development program in mCRPC and initiated a significant workforce reduction in order to focus its development efforts and financial resources on its pivotal phase 3 studies of cabozantinib in metastatic renal cell carcinoma ("RCC") and advanced hepatocellular carcinoma ("HCC"). The Company expects top-line results from METEOR, its phase 3 pivotal trial in RCC, in the second quarter of 2015 and from CELESTIAL, its phase 3 pivotal trial in advanced HCC, in 2017.

The Company will submit the results from the COMET program for potential presentation at a future medical meeting.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to: the Company's plans to focus financial resources on pivotal phase 3 studies of cabozantinib in RCC and HCC; the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib; anticipated developments and timing with respect to the Company's pivotal phase 3 studies of cabozantinib in RCC and HCC; and future potential data presentations. Words such as “focus,” "expects," “will,” “potential,” "future," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon the Company’s current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. The Company’s 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: risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical study; the availability of data at the expected times; the clinical, therapeutic and commercial value of cabozantinib; the Company's ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks and uncertainties related to regulatory review and approval processes and the Company's compliance with applicable legal and regulatory requirements; the general sufficiency of the Company's capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; risks related to the Company's ability to implement the referenced workforce reduction according to plan and its impact on the Company's business; market competition; changes in economic and business conditions; and other factors discussed under the caption “Risk Factors” in the Company’s quarterly report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on November 4, 2014 and in the Company’s 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 . 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.

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.

December 5, 2014	/s/ JEFFREY J. HESSEKIEL
Date	Jeffrey J. Hessekiel
	Executive Vice President, General Counsel and Secretary