EXELIXIS, INC.
Form 8-K
November 22, 2013

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 22, 2013

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, 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.

Exelixis, Inc. (Exelixis) is reporting the expansion by Roche and Genentech, Exelixis collaborator and a member of the Roche Group, of the clinical development program for the MEK inhibitor cobimetinib (GDC-0973/XL518). As disclosed on ClinicalTrials.gov, Roche and Genentech are initiating the following new clinical trials of cobimetinib in combination with other agents:

A Phase 1b, Open-Label, Dose-Escalation Study of the Safety, Tolerability, and Pharmacokinetics of MEHD7945A and Cobimetinib in Patients with Locally Advanced or Metastatic Solid Tumors with Mutant KRAS (NCT01986166);

A Phase 1b, Open-Label Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Onartuzumab in Combination with Vemurafenib and/or Cobimetinib in Patients with Advanced Solid Malignancies (NCT01974258); and

A Phase 1b Study of the Safety and Pharmacology of MPDL3280A Administered with Cobimetinib in Patients with Locally Advanced or Metastatic Solid Tumors (NCT01988896).

These new phase 1b clinical trials are being conducted by Roche and Genentech under Exelixis worldwide co-development agreement with Genentech and are being initiated on the basis of a strong scientific rationale and encouraging preclinical data.

MEHD7945A is a dual specificity antibody targeting EGFR and HER3. Mutation of KRAS and subsequent activation of the MAP kinase pathway independent of EGFR/HER3 may limit the efficacy of agents such as MEHD7945A in KRAS mutant tumors. Co-administration of a MAP kinase inhibitor such as cobimetinib to block signaling downstream of KRAS is therefore a rational combination approach to the treatment of KRAS mutant tumors.

Onartuzumab is an antibody directed against the receptor tyrosine kinase MET. Activation of MET by its ligand HGF limits the response to agents such as vemurafenib (as published by Straussman et. al. in Nature, Volume 487 (19 July 2012), page 500, and Wilson et. al., in Nature, Volume 487 (19 July 2012), page 505), and conversely, activation of MAP kinase via KRAS mutation may limit the efficacy of MET pathway blockade. In preclinical KRAS mutant xenograft models, combinations of onartuzumab and cobimetinib demonstrated superior tumor growth control to either agent administered alone (Yang et. al., poster presented at American Association of Cancer Research Annual Meeting, April 6-10, 2013).

MPDL3280A is an antibody directed against PD-L1, the ligand for PD1. The PD-L1/PD1 pathway restrains T-cell activation in response to tumor antigens. In preclinical syngeneic tumor models, combinations of cobimetinib and an anti-PD-L1 antibody were superior to either agent alone. Notably, cobimetinib did not significantly interfere with T-cell activation in response to PD-L1 inhibition (Irving et. al., poster presented at the Society for Immunotherapy of Cancer Annual Meeting, November 7-10, 2013).

Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug (IND) status. In late 2006, Exelixis entered into the worldwide co-development agreement with Genentech, under which Exelixis received initial upfront and milestone payments for signing the agreement and submitting the IND. Exelixis was responsible for development of cobimetinib through the end of phase 1, at which point Genentech exercised its option to further develop the compound.

Under the terms of the co-development agreement, Exelixis is entitled to an initial equal share of U.S. profits and losses for cobimetinib, which will decrease as sales increase, and will share equally in the U.S. marketing and commercialization costs. The profit share has multiple tiers Exelixis is entitled to 50% of profits from the first $200 million of U.S. actual sales, decreasing to 30% of profits from U.S. actual sales in excess of $400 million. Exelixis is entitled to low double-digit royalties on ex-U.S. net sales. Exelixis also has the option to co-promote in the United States. The co-promotion option would allow Exelixis to provide up to 25% of the total sales force for cobimetinib in the United States. Exelixis must exercise the co-promotion option within 12 months of receiving notification of the first patient dosed in the first phase 3 clinical trial of cobimetinib. Exelixis received notification of dosing from Genentech on January 14, 2013, which triggered the beginning of the period in which Exelixis can exercise its co-promotion option.

Forward-Looking Statements

The statements in this Current Report on Form 8-K regarding the continued development of cobimetinib (GDC-0973/XL518), the plan of Genentech and Exelixis to share U.S. profits and losses for cobimetinib and U.S. marketing and commercialization costs for cobimetinib, Exelixis potential receipt of royalties for cobimetinib products sales outside the United States, and Exelixis option to co-promote in the United States, are 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 cobimetinib to demonstrate safety and efficacy in clinical testing; the availability of data at the expected times; the clinical, therapeutic and commercial value of cobimetinib; Exelixis dependence on its relationship with Roche and Genentech and Exelixis ability to maintain its rights under the collaboration; the uncertainty of regulatory approval processes; 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 three months ended September 27, 2013, filed with the Securities and Exchange Commission on October 30, 2013, 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.

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: November 22, 2013

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