

EXELIXIS, INC.
Form 8-K
July 17, 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): July 11, 2014

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-30235
(Commission

File Number)
210 East Grand Ave.

04-3257395
(IRS Employer

Identification No.)

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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 11, 2014, Genentech, a member of the Roche Group (Genentech), informed Exelixis, Inc. (Exelixis) that the coBRIM study, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring the BRAF^{V600} mutation had met its primary endpoint, delivering a statistically significant increase in progression-free survival for the combination of cobimetinib plus vemurafenib as compared to vemurafenib alone. Cobimetinib is a specific MEK inhibitor that Exelixis outlicensed to Genentech pursuant to a worldwide co-development agreement with Genentech (the Agreement) entered into in December 2006. Genentech further informed Exelixis that adverse events associated with the coBRIM study were consistent with those observed in a previous study of the combination. On July 14, 2014, Exelixis issued a press release, reporting these positive top-line results, as well as Genentech's stated intentions to present these coBRIM data at an upcoming medical meeting and to initiate regulatory filings for the combination before year end.

Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug (IND) status. In late 2006, Exelixis entered into the Agreement, 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 take responsibility for further development of the compound.

Under the terms of the 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. In November 2013, Exelixis exercised an option that will permit it to provide up to 25% of the total sales force for cobimetinib in the United States, if the compound is commercialized, consistent with the Agreement's terms.

Forward-Looking Statements

The statements in this Current Report on Form 8-K regarding future coBRIM data presentations; future regulatory filings for cobimetinib and potential approvals; the extent of Exelixis' future U.S. co-promotion efforts for cobimetinib with Genentech; the plan of Genentech and Exelixis to share U.S. profits and losses for cobimetinib and U.S. marketing and commercialization costs for cobimetinib; and Exelixis' potential receipt of royalties on net sales of cobimetinib products outside 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; the sufficiency of Exelixis' capital and other resources; 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 March 28, 2014, filed with the Securities and Exchange Commission on May 1, 2014, 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 17, 2014

EXELIXIS, INC.

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