

EXELIXIS, INC.
Form 8-K
January 31, 2017

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): January 30, 2017

EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware 0-30235 04-3257395
(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) 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 1.01. Entry into a Material Definitive Agreement.

On January 30, 2017, Exelixis, Inc. (“Exelixis”) and Takeda Pharmaceutical Company Limited (“Takeda”) entered into a collaboration and license agreement (the “Collaboration Agreement”) for the commercialization and further clinical development of cabozantinib in Japan. Pursuant to the terms of the Collaboration Agreement, Takeda will have exclusive commercialization rights for current and potential future cabozantinib indications in Japan. The companies have also agreed to collaborate on the future clinical development of cabozantinib in Japan. The parties’ efforts will be governed through a joint executive committee and appropriate subcommittees established to guide and oversee the collaboration’s operation and strategic direction.

In consideration for the exclusive license and other rights contained in the Collaboration Agreement, Takeda will pay Exelixis an upfront payment of \$50.0 million. Exelixis will be eligible to receive development, regulatory and first-sales milestones of up to \$95.0 million related to second-line renal cell carcinoma (“RCC”), first-line RCC and second-line hepatocellular carcinoma, as well as additional development, regulatory and first-sales milestones payments for potential future indications. The Collaboration Agreement also provides that Exelixis will be eligible to receive pre-specified payments of up to \$83.0 million associated with potential sales milestones. Exelixis will also receive royalties on net sales of cabozantinib in Japan at an initial tiered rate of 15% to 24% on net sales for the first \$300.0 million of cumulative net sales. Thereafter, the royalty rate will be adjusted to 20% to 30% on annual net sales.

Takeda will be responsible for 20% of the costs associated with the global cabozantinib development plan and 100% of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan. Pursuant to the terms of the Collaboration Agreement, Exelixis will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the collaboration. As part of the collaboration, the parties will enter into a supply agreement covering the manufacture and supply of cabozantinib to Takeda and a quality agreement setting forth in detail the quality assurance arrangements and procedures for Exelixis’ manufacture of cabozantinib.

The Collaboration Agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. For clarity, Takeda's failure to achieve specified levels of commercial performance, based upon sales volume and/or promotional effort, during the first six years of the collaboration shall constitute a material breach of the Collaboration Agreement. Exelixis may terminate the agreement if Takeda challenges or opposes any patent covered by the Collaboration Agreement. At any time prior to August 1, 2023, the parties may mutually agree to terminate the Collaboration Agreement if Japan’s Pharmaceuticals and Medical Devices Agency is unlikely to grant approval of the marketing authorization application in any cancer indication in Japan. After the commercial launch of cabozantinib in Japan, Takeda may terminate the Collaboration Agreement upon twelve months’ prior written notice following the third anniversary of the first commercial sale of cabozantinib in Japan. Upon termination by either party, all licenses granted by Exelixis to Takeda will automatically terminate, and the licenses granted by Takeda to Exelixis shall survive such termination and shall automatically become worldwide.

The description of the Agreement in this Current Report on Form 8-K does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be included as an exhibit to Exelixis’ Quarterly Report on Form 10-Q for the fiscal period ending March 31, 2017, to be filed with the Securities and Exchange Commission (“SEC”).

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to: the payment to Exelixis of an upfront payment; Exelixis’ potential receipt of regulatory and sales

milestones, as well as royalties on sales of products. 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: that Takeda may not perform under the Collaboration Agreement as Exelixis expects. Other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q filed with the SEC on November 3, 2016, and in Exelixis' future filings with the SEC. 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.

January 31, 2017 /s/ JEFFREY J. HESSEKIEL

Date Jeffrey J. Hessekiel
Executive Vice President and General Counsel