

EXELIXIS INC
Form 8-K
December 22, 2011

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 22, 2011

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

0-30235
(Commission

File Number)

04-3257395
(IRS Employer

Identification No.)

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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 1.01. Entry into a Material Definitive Agreement.

On December 22, 2011, Exelixis, Inc. (the "Company") and Sanofi entered into an agreement (the "Termination Agreement") pursuant to which the parties mutually agreed to terminate the Collaboration Agreement dated as of May 27, 2009 and effective as of July 7, 2009 by and between the Company and Sanofi for the discovery of inhibitors of Phosphoinositide-3 Kinase ("PI3K") alpha and beta (the "Collaboration Agreement"). The termination of the Collaboration Agreement pursuant to the Termination Agreement is effective as of the end of the day on December 22, 2011. The parties mutually agreed to terminate the Collaboration Agreement in light of the Company's announcement in 2010 to focus its resources and development efforts on cabozantinib (XL184), the Company's most advanced compound.

Under the Collaboration Agreement, the parties had agreed to combine efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K-α and -β. Sanofi was required to provide the Company with guaranteed annual research funding during the research term and was responsible for funding all development activities for each product following approval of the investigational new drug, or IND, application that might have been filed with the applicable regulatory authorities for such product. The Company was entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of its costs under the Collaboration Agreement. Sanofi had sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, Sanofi could request that the Company conduct certain clinical trials at Sanofi's expense. The research term under the collaboration was originally three years, although Sanofi had the right to extend the term for an additional one-year period upon prior written notice, or terminate the Collaboration Agreement early under certain circumstances. The Company was eligible to receive development, regulatory and commercial milestones, as well as royalties on sales of any products commercialized under the Collaboration Agreement. The Collaboration Agreement would have automatically terminated under certain circumstances upon the expiration of the research term, in which case all licenses granted by a party to the other party would have terminated and reverted to the respective granting party, except that Sanofi would have retained the right to receive, under certain circumstances, the first opportunity to obtain a license from the Company to any isoform-selective PI3K inhibitor. In addition, after expiration of the research term, Sanofi had the right, upon certain prior written notice to the Company, to terminate the Collaboration Agreement in whole or as to particular products, in which case the Company would have received, subject to certain terms, conditions and obligations for the Company to make payments to Sanofi, exclusive licenses from Sanofi to research, develop and commercialize such products.

Pursuant to the terms of the Termination Agreement, the parties have terminated the Collaboration Agreement and released each other from any potential liabilities arising under the Collaboration Agreement prior to the termination effective date. Each party retains ownership of the intellectual property that it generated under the Collaboration Agreement, and Exelixis has granted Sanofi covenants not-to-enforce with respect to certain of Exelixis' intellectual property rights. The Termination Agreement also provides that Sanofi will make a payment to the Company of \$15,250,000 within 10 business days after the termination effective date. If either party or its affiliate or licensee develops and commercializes a therapeutic product containing an isoform-selective PI3K inhibitor that arose from such party's work (or was derived from such work) under the Collaboration Agreement, then such party will be obligated to pay royalties to the other party based upon the net sales of such products. The Termination Agreement provides that Sanofi will make a one-time milestone payment to the Company upon the first receipt by Sanofi or its affiliate or licensee of marketing approval for the first therapeutic product containing an isoform-selective PI3K inhibitor that arose from Sanofi's work (or was derived from such work) under the Collaboration Agreement.

The Company and Sanofi are, and remain, parties to a global license agreement for the development and commercialization of XL147 (SAR245408) and XL765 (SAR245409), PI3K inhibitors that are in clinical development (the "License Agreement"). A summary of the material terms of the license agreement is included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

The description of the Termination 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 complete Termination Agreement, a copy of which will be included as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 30, 2011 to be filed with the Securities and Exchange Commission.

Item 1.02. Termination of a Material Definitive Agreement.

The information set forth under Item 1.01 of this Current Report on Form 8-K is hereby incorporated into this Item 1.02 by reference.

Item 7.01. Regulation FD Disclosure.

For purposes of recognizing up-front payments received under the Collaboration Agreement and the License Agreement, prior to the effectiveness of the Termination Agreement the Company was recognizing revenue through the end of the research term, which was estimated to be July 2013. As a result of the termination of the Collaboration Agreement, the estimated research term will now end as of the end of the day on December 22, 2011. Accordingly, the Company expects to accelerate the remaining deferred revenue balance relating to the up-front payments under the Collaboration Agreement and the License Agreement and estimates that it will recognize an aggregate of approximately \$74 million in revenue in the fourth fiscal quarter of 2011, of which approximately \$63 million was not included in the Company's prior guidance as to its financial results for 2011 and is due to such acceleration and the termination payment pursuant to the Termination Agreement.

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: December 22, 2011

/s/ JAMES B. BUCHER
James B. Bucher

Vice President, Corporate Legal Affairs and Secretary