EXELIXIS INC
Form 8-K
May 28, 2009

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): May 27, 2009

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-30235**	**04-3257395**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

249 East Grand Ave.

P.O. Box 511

South San Francisco, California 94083-0511

(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 May 27, 2009, Exelixis, Inc. (Exelixis) entered into a global license agreement with sanofi-aventis for two of Exelixis cancer programs, XL147 and XL765, and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase (PI3K) for the treatment of cancer. Activation of the PI3K pathway is a frequent event in human tumors, promoting cell proliferation, survival, and resistance to chemotherapy and radiotherapy.

Under the license, sanofi-aventis will have a worldwide exclusive license to XL147 and XL765, which are currently in phase 1 and phase 1b/2 clinical trials, and will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. Exelixis will participate in conducting ongoing and potential future clinical trials and manufacturing activities. Sanofi-aventis will be responsible for funding all future development activities with respect to XL147 and XL765, including Exelixis activities.

Under the discovery collaboration, Exelixis and sanofi-aventis will 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 alpha and beta. Sanofi-aventis will provide guaranteed R&D funding to cover Exelixis expenses and will be responsible for funding all development activities for each product following approval of the investigational new drug application filed with the United States Food and Drug Administration, or the foreign equivalent thereof, for such product. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, Exelixis may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

Upon effectiveness of the license and collaboration, sanofi-aventis is required pay Exelixis aggregate upfront cash payments of $140.0 million ($120 million for the license and $20 million for the collaboration). Exelixis is also entitled to receive guaranteed research funding of $21.0 million over the three year research term under the collaboration. For both the license and the collaboration, Exelixis will be eligible to receive development, regulatory and commercial milestones of over $1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license or collaboration.

Sanofi-aventis may, upon certain prior notice to Exelixis, terminate the license as to products containing XL147 or XL765. In the event of such termination election, sanofi-aventis license relating to such product would terminate and revert to Exelixis, and Exelixis would receive, subject to certain terms, conditions and potential payment obligations by Exelixis, licenses from sanofi-aventis to research, develop and commercialize such products.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other would terminate and revert to the respective party, subject to sanofi-aventis right to receive, under certain circumstances, the first opportunity to obtain a license from Exelixis to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to Exelixis, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case Exelixis would receive, subject to certain terms, conditions and potential payment obligations by Exelixis, licenses from sanofi-aventis to research, develop and commercialize such products.

The effectiveness of the agreements is subject to and will become effective upon clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of other customary regulatory approvals.

The aggregate upfront payments of $140.0 million Exelixis expects to receive upon effectiveness of the agreements will be recognized over an estimated term of four years, and recorded as license revenue, from the effective date of the agreements. Any milestone payments that Exelixis may receive under the agreements will be amortized over the same period but recorded as contract revenue. Exelixis will record as operating expense all costs incurred for work performed by Exelixis under the agreements. Reimbursements Exelixis receives from sanofi-aventis under the agreements will be recorded as contract revenue commencing as of the effective date, including reimbursements for costs incurred under the license from the date of signing. In addition, the guaranteed research funding that Exelixis expects to receive over the three year research term under the collaboration will be recorded as contract revenue commencing as of the effective date of the collaboration.

This Current Report on Form 8-K contains forward-looking statements by Exelixis, including, without limitation, statements related to the anticipated effectiveness of the license and collaboration described in this report; the companies plan for sanofi-aventis to have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities with respect to XL147 and XL765 and for Exelixis to participate in conducting ongoing and potential future clinical trials and manufacturing activities; the companies plan to combine efforts in establishing pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities under the collaboration; the companies plans for sanofi-aventis to have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration and for Exelixis to potentially have responsibility for conducting certain clinical trials; Exelixis receipt of upfront payments and guaranteed research funding; Exelixis potential receipt of development, regulatory and commercial milestones, as well as royalties on sales of any products commercialized under the license or collaboration; and the future development path and commercial and therapeutic potential of XL147, XL765 and other potential PI3K inhibitors. Exelixis expectations regarding the accounting treatment for payments it receives and costs it incurs under the agreements. Words such as will, may, eligible, believe, suggest, potential and similar expressions are intended to identify 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 XL147, XL765 and other potential PI3K inhibitors to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of XL147, XL765 and other potential PI3K inhibitors; the uncertainty of the FDA approval process; market competition; and Exelixis dependence on its relationship with its collaboration partners. These and other risk factors are discussed under Risk Factors in Exelixis Quarterly Report for the quarter ended April 3, 2009 and Exelixis other reports filed 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: May 28, 2009

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