EXELIXIS INC
Form 8-K
April 25, 2007

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): April 20, 2007

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.)**

170 Harbor Way

P.O. Box 511

South San Francisco, California 94083

(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

On April 20, 2007, Exelixis, Inc. (the Company) was notified by the U.S. Food and Drug Administration (FDA) that it has completed its review of a clinical trial protocol for XL999 in patients with non-small cell lung cancer (NSCLC) and has agreed that the trial may be initiated.

This clinical trial will evaluate XL999 in patients with NSCLC who have failed at least one previous therapy. The trial will have a dose-escalation format starting at 0.4 mg/kg dosed weekly, while monitoring patients for potential cardiovascular events. Results from this Phase 1 clinical trial could provide the Company with the opportunity to move directly into a late stage clinical trial if XL999 demonstrates anti-tumor activity with an acceptable side-effect profile in this well-defined NSCLC patient population.

XL999 was previously evaluated in Phase 1 and 2 clinical trials in which cardiovascular adverse events were observed. These observations caused the Company to suspend new patient enrollment in the ongoing XL999 clinical trials in November 2006. The FDA subsequently placed the clinical program on partial clinical hold in December 2006. The previous Phase 1 and 2 clinical trials will not be re-initiated at this time. Given acceptance by the FDA of the new clinical trial protocol for XL999 in patients with NSCLC, the XL999 development program will now focus on this indication.

This Form 8-K contains forward-looking statements, including without limitation statements related to the future development and potential efficacy of XL999. Words such as believes, anticipates, plans, expects, intends, will, slated, goal and similar expressions are intend forward-looking statements. These forward-looking statements are based upon the Company s current expectations. Forward-looking statements involve risks and uncertainties. The Company s 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 lengthy, costly and uncertain process of clinical testing of XL999 and the potential failure to demonstrate safety and efficacy and the therapeutic and commercial potential of XL999. These and other risk factors are discussed under Risk Factors and elsewhere in the Company s Annual Report on Form 10-K for the year ended December 29, 2006 and other filings with the Securities and Exchange Commission. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company s 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.

Dated: April 25, 2007

Exelixis, Inc.

/s/ Pamela A. Simonton
Pamela A. Simonton, J.D., LL.M.
Senior Vice President, Patents and Licensing.