EXELIXIS INC
Form 8-K
December 12, 2008

# 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 11, 2008

# 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 1.01 Entry into a Material Definitive Agreement.**

On December 11, 2008, Exelixis, Inc. ( Exelixis or the Company ) entered into a worldwide collaboration with Bristol-Myers Squibb Company ( BMS ) on two of Exelixis novel cancer programs: one associated with XL184, which is currently in Phase III development for medullary thyroid cancer, and the other associated with XL281, which is currently in Phase I development for the treatment of patients with advanced solid tumor malignancies.

Upon effectiveness of the agreement, BMS is required to pay Exelixis an upfront cash payment of $195 million for the development and commercialization rights to both programs. BMS is also required to make additional license payments of $45 million in 2009.

Exelixis and BMS have agreed to co-develop XL184, which may include a backup program for XL184 to be agreed upon by the parties. The companies will share worldwide (except for Japan) development costs for XL184. Exelixis will be responsible for 35% of such costs and BMS will be responsible for 65% of such costs, except that Exelixis will be responsible to fund the initial $100 million of such costs and will have the option to defer payments for development costs above certain thresholds. In return, Exelixis will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and will have the option to co-promote XL184 in the United States. Exelixis may have the right to defer payment for certain early commercialization and other related costs above certain thresholds. Exelixis will be eligible to receive sales performance milestones of up to $150 million and royalties on sales on XL184 outside the United States. The clinical development of XL184 will be directed by a joint committee. It is anticipated that Exelixis will conduct certain clinical development activities for XL184. Exelixis may opt out of the co-development for XL184, in which case Exelixis would instead be eligible to receive development and regulatory milestones of up to $295 million, royalties on XL184 product sales worldwide and sales performance milestones. Exelixis co-development and co-promotion rights may be terminated in the event that Exelixis has cash reserves below $80 million and Exelixis is unable to increase such cash reserves to $80 million or more within 90 days, in which case Exelixis would receive development and regulatory milestones, sales milestones and royalties, instead of sharing product profits on XL184. For purposes of the agreement, cash reserves includes Exelixis total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by Exelixis under the Facility Agreement dated June 4, 2008 among Exelixis, Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited, as the same may be amended from time to time, and any other similar financing arrangements. Exelixis co-promotion rights on XL184 in the United States, but not its right to share product profits on XL184, may be terminated in the event Exelixis undergoes a change of control transaction.

BMS will receive an exclusive worldwide license to develop and commercialize XL281. Exelixis will carry out certain clinical trials of XL281 and may conduct a backup program on XL281 to be agreed upon by the parties. BMS will be responsible for funding all future development on XL281, including Exelixis activities. Exelixis is eligible for development and regulatory milestones of up to $315 million on XL281, sales performance milestones of up to $150 million and royalties on worldwide sales of XL281.

The transaction is subject to and will become effective upon clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended.

*This Current Report on Form 8-K contains forward-looking statements by Exelixis, including, without limitation, statements related to the anticipated effectiveness of the agreement described in this report and Exelixis receipt of an upfront cash payment from Bristol-Myers Squibb; potential license and milestone payments by Bristol-Myers Squibb to Exelixis; the companies plan to share development costs and commercial profits and losses for XL184 in the United States; Exelixis potential receipt of royalties for XL184 product sales; Exelixis right to opt out of the co-development and co-promotion of XL184 in the United States and the related impact on potential royalties and milestones; Exelixis potential receipt of development, regulatory and sales milestones and royalties on worldwide sales of XL281; and the future funding, development path and commercial and therapeutic potential of XL184 and XL281 and associated compounds. Words such as will, anticipated, eligible, would 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 XL184 and XL281 to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of XL184 and XL281; the uncertainty of the FDA approval process; market competition; and Exelixis dependence on its relationship with Bristol-Myers Squibb and ability to maintain its co-development rights under the collaboration. These and other risk factors are discussed under Risk Factors and elsewhere in Exelixis quarterly report on Form 10-Q for the quarter ended September 26, 2008 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.*

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 12, 2008

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