

EXELIXIS INC
Form 8-K
October 12, 2010

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): October 8, 2010

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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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 October 8, 2010, Exelixis, Inc. ("Exelixis") entered into new agreements with Bristol-Myers Squibb Company ("Bristol-Myers Squibb") relating to two of Exelixis' programs. Under the first agreement, Exelixis will grant to Bristol-Myers Squibb a license to its small-molecule TGR5 agonist program, including rights to the program's lead compound, XL475, as well as potential backups. Under the second agreement, the companies will collaborate to discover, optimize, and characterize ROR antagonists. Exelixis simultaneously amended three of its existing collaboration agreements with Bristol-Myers Squibb for the treatment of cancer, cardiovascular and metabolic disorders, each as more fully described below.

TGR5 License Agreement

Exelixis entered into a global license agreement with Bristol-Myers Squibb for XL475 (and any potential backups), a preclinical compound that modulates the metabolic target known as TGR5 (the "TGR5 License Agreement"). Pursuant to the terms of the TGR5 License Agreement, Bristol-Myers Squibb will have a worldwide exclusive license to XL475 and will have sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. Upon effectiveness of the TGR5 License Agreement, Bristol-Myers Squibb is required to pay Exelixis an upfront cash payment of \$35.0 million. Additionally, for each product developed by Bristol-Myers Squibb under the license, Exelixis will be eligible to receive development and regulatory milestones of up to \$250.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Bristol-Myers Squibb may at any time, upon specified prior notice to Exelixis, terminate the license on a product-by-product and country-by-country basis. In addition, either Party may terminate the agreement for the other party's uncured material breach. In the event of termination by Bristol-Myers Squibb at will or by Exelixis for Bristol-Myers Squibb's uncured material breach, the license granted to Bristol-Myers Squibb would terminate, the right to such product would revert to Exelixis, and Exelixis would receive a royalty-free license, if terminated at will, or a royalty-bearing license, if terminated for an uncured material breach, from Bristol-Myers Squibb to develop and commercialize such product in the related country. In the event of termination by Bristol-Myers Squibb for Exelixis' uncured material breach, Bristol-Myers Squibb would retain the right to such product and Exelixis would receive reduced royalties from Bristol-Myers Squibb on commercial sales of such product.

The TGR5 License Agreement is subject to and will become effective upon clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended.

The description of the TGR5 License 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 copy of the TGR5 License 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 31, 2010 to be filed with the Securities and Exchange Commission.

ROR Collaboration Agreement

Exelixis entered into a worldwide collaboration with Bristol-Myers Squibb pursuant to which each party granted to the other certain intellectual property licenses to enable the parties to discover, optimize and characterize ROR antagonists that may subsequently be developed and commercialized by Bristol-Myers Squibb (the "ROR Collaboration Agreement"). Bristol-Myers Squibb is required to pay Exelixis an upfront cash payment of \$5.0 million in connection with the ROR Collaboration Agreement. Additionally, for each product developed by Bristol-Myers Squibb under the license, Exelixis will be eligible to receive development and regulatory milestones of up to \$255.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Under the terms of the ROR Collaboration Agreement, Exelixis will be primarily responsible for activities related to the discovery, optimization and characterization of the ROR antagonists during the collaborative research period. The collaborative research period will begin upon the effective date of the ROR Collaboration Agreement and will end on the earliest to occur of (i) October 8, 2013 if a compound has not satisfied certain specified criteria by such time, (ii) such time that a compound satisfies certain specified criteria, or (iii) October 8, 2015. Following the collaborative research period, Bristol-Myers Squibb will have sole responsibility for any further research, development, manufacture and commercialization of products developed under the collaboration and will bear all costs and expenses associated with those activities.

Bristol-Myers Squibb may, at any time, terminate the ROR Collaboration Agreement upon certain prior notice to Exelixis. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Bristol-Myers Squibb at will or by Exelixis for Bristol-Myers Squibb's uncured material breach, the license granted to Bristol-Myers Squibb would terminate, the right to such product would revert to Exelixis, and Exelixis would receive a royalty-bearing license for

late-stage reverted compounds and a royalty-free license for early-stage reverted compounds from Bristol-Myers Squibb to develop and commercialize such product in the related country. In the event of termination by Bristol-Myers Squibb for Exelixis' uncured material breach, Bristol-Myers Squibb would retain the right to such product, subject to continued payment of milestones and royalties.

The ROR Collaboration Agreement became effective on October 8, 2010.

The description of the ROR Collaboration 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 copy of the ROR Collaboration 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 31, 2010 to be filed with the Securities and Exchange Commission.

Amendment to 2008 Cancer Collaboration

Exelixis and Bristol-Myers Squibb entered into Amendment No. 3 to the existing collaboration agreement between the parties dated December 11, 2008, as amended (the "2008 Cancer Collaboration Agreement"), pursuant to which the parties made certain minor amendments to the rights and obligations of the parties under the 2008 Collaboration agreement with respect to XL281.

Amendment No. 3 to the 2008 Cancer Collaboration Agreement became effective on October 8, 2010.

The description of Amendment No. 3 to the 2008 Cancer Collaboration 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 copy of the 2008 Cancer Collaboration Agreement previously filed with the Securities and Exchange Commission, including all amendments and modifications thereto previously filed with the Securities and Exchange Commission, and the Amendment No. 3 thereto, 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 31, 2010 to be filed with the Securities and Exchange Commission.

Amendment to 2007 Cancer Collaboration

Exelixis and Bristol-Myers Squibb entered into Amendment No. 3 to the existing collaboration agreement between the parties dated December 15, 2006, which became effective on January 11, 2007, as amended (the "2007 Cancer Collaboration Agreement"), pursuant to which Exelixis exercised its right to opt-out of further co-development of XL139 in consideration for a payment of \$20.0 million. Upon the effectiveness of Amendment No. 3 to the 2007 Cancer Collaboration Agreement, Exelixis will have no further responsibility for conducting new activities or funding new development or commercialization activities with respect to XL139 and will therefore no longer be eligible to share profits on sales of any commercialized products under the collaboration. Exelixis will continue to be eligible to receive regulatory and commercial milestones as well as double-digit royalties on any future sales of any products commercialized under the collaboration. As a result of the amendment, the research term will end, and Exelixis will have no further obligation to deliver to Bristol-Myers Squibb a third Investigational New Drug candidate under the 2007 Cancer Collaboration Agreement.

Amendment No. 3 to the 2007 Cancer Collaboration Agreement is subject to and will become effective upon clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended.

The description of Amendment No. 3 to the 2007 Cancer Collaboration 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 copy of the 2007 Cancer Collaboration Agreement previously filed with the Securities and Exchange Commission, including all amendments and modifications thereto previously filed with the Securities and Exchange Commission, and the Amendment No. 3 thereto, 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 31, 2010 to be filed with the Securities and Exchange Commission.

Amendment to LXR Collaboration

Exelixis and Bristol-Myers Squibb entered into Amendment No. 1 to the existing collaboration agreement between the parties dated December 5, 2005, as amended (the "LXR Collaboration Agreement"), pursuant to which the parties made certain minor amendments to the rights and obligations of the parties under the LXR Collaboration agreement.

Amendment No. 1 to the LXR Collaboration Agreement became effective on October 8, 2010.

The description of Amendment No. 1 to the LXR Collaboration 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 copy of the LXR Collaboration Agreement previously filed with the Securities and Exchange Commission, including all amendments and modifications thereto previously filed with the Securities and Exchange Commission, and the Amendment No. 1 thereto, 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 31, 2010 to be filed with the Securities and Exchange Commission.

Accounting Treatment

The TGR5 License Agreement, ROR Collaboration Agreement and Amendment No. 3 to the 2007 Cancer Collaboration Agreement will be accounted for as one unit of accounting with the revenue from all agreements being recognized over the longest commitment period. The ROR Collaboration Agreement has the longest commitment period of the three agreements with a research term of approximately 42 months. Therefore, we expect to recognize the upfront payments received under the TGR5 License Agreement and the ROR Collaboration Agreement ratably over approximately 42 months and to record them as license revenue.

The payment to be received under the Amendment No. 3 to the 2007 Cancer Collaboration Agreement will be added to the deferred revenue balance remaining as of the effective date of the amendment and we expect to recognize the combined total ratably over approximately 42 months and to record them as contract revenue.

For illustrative purposes, if the agreements become effective during the fourth quarter of 2010, we estimate the total incremental revenue related to the new and amended agreements in 2010 and 2011 will be approximately \$0.9 million and \$8.5 million, respectively. Any milestone payments that we may receive under any of the agreements will be recognized in accordance with our existing policy as contract revenue ratably over the remaining commitment period under the agreements.

Any costs incurred in connection with the ROR Collaboration Agreement or TGR5 License Agreement will be recorded as operating expense.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements by Exelixis, including, without limitation, statements related to the anticipated effectiveness of the amendment to the 2007 Cancer Collaboration Agreement and collaboration agreements described in this report; the companies' plan for Bristol-Myers Squibb to have sole control and responsibility for all subsequent research, development, commercial and manufacturing activities of any products arising from the TGR5 License Agreement; Exelixis' receipt of upfront payments and the payment for opting out of XL139; Exelixis' potential receipt of development, regulatory and commercial milestones, as well as royalties on sales of any products commercialized; the respective future responsibilities of the parties under the ROR Collaboration Agreement; the expected accounting treatment for the agreements described in this report; and the future development path and commercial and therapeutic potential of XL475, XL281, XL139 and other Exelixis compounds. Words such as will, would, eligible, potential, expect, estimate, may 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 Exelixis' dependence on the activities of Bristol-Myers Squibb under the described agreements, the potential failure of XL475, XL281, XL139 and other Exelixis compounds to demonstrate safety and efficacy in clinical testing; unanticipated changes in accounting rules; the therapeutic and commercial value of XL475, XL281, XL139 and other Exelixis compounds; the uncertainty of the FDA approval process, market competition and changes in economic and business conditions. These and other risk factors are discussed under Risk Factors in Exelixis' Quarterly Report for the quarter ended July 2, 2010 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: October 12, 2010

/s/ JAMES B. BUCHER

James B. Bucher

Vice President, Corporate Legal Affairs and Secretary