EXELIXIS, INC.
Form 8-K
September 05, 2014

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): August 31, 2014

EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware	000-30235	04-3257395
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

210 East Grand Ave.
South San Francisco, California 94080
(Address of principal executive offices) (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 2.05 Costs Associated with Exit or Disposal Activities.

On August 31, 2014, the Board of Directors of Exelixis, Inc. (the "Company") approved a restructuring plan, which was implemented on September 2, 2014, resulting in a reduction of the Company's workforce by approximately 70%, or approximately 155 employees, resulting in approximately 75 remaining employees. Personnel reductions have been made across the Company's entire organization. The restructuring plan is a consequence of the failure of COMET-1, the Company's phase 3 pivotal trial of cabozantinib in men with metastatic castration-resistant prostate cancer ("mCRPC") whose disease progressed after treatment with docetaxel as well as abiraterone and/or enzalutamide, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival ("OS") for patients treated with cabozantinib as compared to prednisone. The principal objective of the restructuring plan is to enable the Company to focus its financial resources on the phase 3 pivotal trials of cabozantinib in metastatic renal cell carcinoma (the METEOR trial) and advanced hepatocellular carcinoma (the CELESTIAL trial), for which the Company expects top-line results in 2015 and 2017, respectively. As a result of the restructuring plan and other cost-saving measures contemplated, the Company anticipates that it has sufficient cash resources to support its operations through the release of top-line results of the METEOR trial.

The Company expects to record an aggregate restructuring charge related to one-time termination benefits in the range of approximately $6 million to $8 million, of which approximately 90% is expected in the fourth quarter of 2014 and the remainder is expected in the first quarter of 2015. The Company expects to incur additional charges as a result of the restructuring plan, including facility-related charges, equipment write-downs and potentially other charges, and expects to record the majority of these expenses during the fiscal year 2014 as they are determined. The Company is currently unable to estimate the total amount or range of amounts expected to be incurred in connection with the restructuring plan for each major type of cost or in the aggregate. The Company expects that the restructuring plan will result in aggregate cash expenditures of approximately $16 million, of which approximately $2 million is expected in the third quarter of 2014, $13 million is expected in the fourth quarter of 2014 and the remainder is expected in the first quarter of 2015. These cash expenditures consist of: (i) salary and benefits expected to be paid to terminated employees during the period from the implementation date of the restructuring plan through their termination dates, which are expected to commence in early November 2014, reflecting the 60-day notice period required under the federal Worker Adjustment and Retraining Notification Act (the "WARN Period"); and (ii) payments for cash severance, accrued vacation, outplacement services, and other benefits expected to paid to terminated employees upon termination. Salary and benefits paid to terminated employees during the WARN Period will be recorded as operating expenses.

As described above, the Company is currently unable in good faith to make a determination of the estimates or range of estimates required by paragraphs (b), (c) and (d) of Item 2.05 of Form 8-K. As permitted by Item 2.05 of Form 8-K, the Company will file an amendment to this Report under Item 2.05 within four business days after the Company's determination of such an estimate or range of estimates.

The restructuring charge that the Company expects to incur in connection with the restructuring is subject to a number of assumptions, and actual results may materially differ. The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring plan.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

In connection with the restructuring plan described in Item 2.05 of this Report, J. Scott Garland, the Company's Executive Vice President and Chief Commercial Officer, and the Company have reached mutual agreement as to his separation from the Company, effective as of November 3, 2014 (the "Separation Date"). Pursuant to the terms of the Exelixis, Inc. Change in Control and Severance Benefits Plan, as of the Separation Date Mr. Garland will be entitled to receive from the Company, in exchange for Mr. Garland's general release of claims: (i) a cash benefit equal to six months of base salary paid in installments pursuant to the Company's regularly scheduled payroll periods; and (ii) payment of COBRA premiums, or the cash equivalent thereof, for a period of up to six months for any health, dental or vision plan sponsored by the Company in which Mr. Garland is enrolled.

Item 8.01 Other Events.

On September 1, 2014, the Company announced top-line results from the final analysis of COMET-1, the Company's phase 3 pivotal trial of cabozantinib in men with metastatic castration-resistant prostate cancer ("mCRPC") whose disease progressed after treatment with docetaxel as well as abiraterone and/or enzalutamide. The trial did not meet its primary endpoint of demonstrating a statistically significant increase in overall survival ("OS") for patients treated with cabozantinib as compared to prednisone. The median OS for the cabozantinib arm of the trial was 11.0 months versus 9.8 months for the prednisone arm (hazard ratio 0.90; 95% confidence interval 0.76 - 1.06; p value 0.212).

The COMET-1 results are the subject of ongoing analyses. The Company plans to submit additional data, including secondary and exploratory endpoints, for presentation at a future medical conference. Besides OS, the exploratory endpoint of progression-free survival ("PFS") as assessed by the investigators is the only time-to-event-based endpoint for which data currently are available. Median PFS was 5.5 months for the cabozantinib arm of the trial versus 2.8 months for the prednisone arm (hazard ratio 0.50; 95% confidence interval 0.42 - 0.60; p value <0.0001). Safety data were consistent with those observed in earlier-stage trials of cabozantinib in mCRPC.

Based on the outcome of COMET-1, the Company has deprioritized the clinical development of cabozantinib in mCRPC. Enrollment in COMET-2, the Company's second pivotal trial in mCRPC and evaluates pain palliation, has been halted. The Company expects top-line data before the end of 2014. Based on the outcome of COMET-2, the Company intends to discuss with regulatory authorities the potential regulatory path, if any, of cabozantinib in mCRPC. Other Company-sponsored studies in mCRPC, including a randomized phase 2 study of cabozantinib in combination with abiraterone, will also be halted.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to: the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib; the results and implications of completed, partial, and ongoing clinical data analyses; future data presentations; future discussions with regulatory authorities; anticipated developments and timing with respect to the Company's ongoing phase 3 pivotal trials of cabozantinib; plans to focus financial resources, to halt company-sponsored studies in mCRPC; and the implementation of the referenced restructuring plan, including the expected charges, expenses, and cash expenditures relating thereto and the objectives and anticipated timing thereof. Words such as "will," "intends," "enable," "focus," "anticipates," "expect," "potential," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon the Company's current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the availability of data at the expected times; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical study; the clinical, therapeutic and commercial value of cabozantinib; the Company's ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks and uncertainties related to regulatory review and approval processes and the Company's compliance with applicable legal and regulatory requirements; the general sufficiency of the Company's capital and other resources and the specific risk of unforeseen expenses that could diminish the Company's financial ability to support its operations through the release of top-line METEOR results; the uncertain timing and level of expenses associated with the development of cabozantinib; risks related to the Company's ability to implement the referenced workforce reduction according to plan and its impact on the Company's business; charges, expenses and cash expenditures resulting from the referenced workforce reduction; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in the Company's quarterly report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on July 31, 2014 and in the Company's other filings with the SEC. The forward-looking statements made in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K . The Company 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 the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based, except for the obligation to amend Item 2.05 of this Current Report on Form 8-K following a determination of the estimates or range of estimates required by paragraphs (b), (c) and (d) of Item 2.05 of Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 5, 2014 EXELIXIS, INC.

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