

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 25, 2019



EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-30235
(Commission
File Number)

04-3257395
(IRS Employer
Identification No.)

1851 Harbor Bay Parkway
Alameda, California 94502
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On April 25, 2019, Exelixis, Inc. made the following disclosure:

Following Bristol-Myers Squibb's First Quarter 2019 financial results call, we are clarifying the update provided on the status and plans for the CheckMate 9ER study. CheckMate 9ER recently completed enrollment, including in Japan where the last few patients are in the process of being randomized. Ultimately the trial will randomize approximately 650 patients globally, which will provide additional power to the study. As the study analyses are event-driven, data is now expected in early 2020. As a reminder, the primary endpoint for CheckMate 9ER is progression free survival (PFS), and overall survival (OS) is a secondary endpoint. We are not commenting further on the statistical plan nor on any potential interim analyses.

The statements above regarding the number of patients expected in the trial and the timing of expected data are forward-looking statements subject to risks and uncertainties, including those risks discussed under the caption "Risk Factors" in Exelixis' Annual Report on Form 10-K for the year ended December 28, 2018, filed with the Securities and Exchange Commission on February 22, 2019. Exelixis undertakes no duty to update these statements other than to the extent required by applicable law.

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.

EXELIXIS, INC.

April 25, 2019

Date

/s/ JEFFREY J. HESSEKIEL

Jeffrey J. Hessekiel

Executive Vice President and General Counsel