

**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): September 2, 2022



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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock \$.001 Par Value per Share	EXEL	The Nasdaq Stock Market LLC

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 8.01 Other Events

On September 2, 2022, Exelixis, Inc. (Exelixis) filed a complaint in the United States District Court for the District of Delaware (the Delaware District Court) for patent infringement against Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), asserting infringement of U.S. Patent No. 11,298,349 (the September 2022 Teva ANDA Complaint) arising from Teva's amendment of its Abbreviated New Drug Application (ANDA). In May 2021, Exelixis received notice that Teva had filed an ANDA with the U.S. Food and Drug Administration (FDA) for a generic version of CABOMETYX® (cabozantinib) tablets (20 mg / 40 mg / 60 mg). Exelixis received notice on July 29, 2022, that Teva had filed a Paragraph IV certification against U.S. Patent No. 11,298,349, and as amended, Teva's ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of U.S. Patent No. 11,298,349. In the September 2022 Teva ANDA Complaint, Exelixis is seeking, among other remedies, equitable relief enjoining Teva from infringing U.S. Patent No. 11,298,349, as well as an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of U.S. Patent No. 11,298,349 on February 10, 2032. The September 2022 Teva ANDA Complaint is Exelixis' second case against Teva and involves an Exelixis patent that is different from those asserted in Civil Action No. 21-00871 (the 2021 Teva ANDA Action), which is described below. A trial has not yet been scheduled in connection with the September 2022 Teva ANDA Complaint.

The 2021 Teva ANDA Action arises from a complaint filed by Exelixis against Teva in June 2021, asserting infringement of U.S. Patents No. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. The 2021 Teva ANDA Action was scheduled for a bench trial in June 2023; however, in February 2022, the parties filed a stipulation to stay all proceedings, which was entered by the Delaware District Court, and this case was administratively closed. Exelixis is seeking, among other remedies, equitable relief enjoining Teva from infringing U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757, as well as an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the patents at issue in the 2021 Teva ANDA Action, the latest of which expires on July 9, 2033.

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.

September 2, 2022

Date

/s/ JEFFREY J. HESSEKIEL

Jeffrey J. Hessekiel
Executive Vice President, General Counsel
and Secretary