

**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): July 18, 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 July 18, 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 MSN Pharmaceuticals, Inc. (MSN) asserting infringement of U.S. Patent No. 11,298,349 (the July 2022 MSN ANDA Complaint) arising from MSN's further amendment of its Abbreviated New Drug Application (ANDA), originally filed with the U.S. Food and Drug Administration (FDA) in September 2019 for a generic version of CABOMETYX® (cabozantinib) tablets (20 mg / 40 mg / 60 mg). Exelixis received notice on June 7, 2022, that MSN had filed a paragraph IV certification against U.S. Patent No. 11,298,349, and as further amended, MSN'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 July 2022 MSN ANDA Complaint, Exelixis is seeking, among other remedies, equitable relief enjoining MSN from infringing U.S. Patent No. 11,298,349, as well as an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of U.S. Patent No. 11,298,349 on February 10, 2032. The July 2022 MSN ANDA Complaint is Exelixis' fourth case against MSN and involves an Exelixis patent that is different from those asserted in consolidated Civil Action Nos. 19-2017 and 20-00633 (collectively, the 2019/2020 MSN ANDA Actions) and separate Civil Action No. 22-00228 (the February 2022 MSN ANDA Action), each of which is described below. A trial has not yet been scheduled in connection with the July 2022 MSN ANDA Complaint.

The 2019/2020 MSN ANDA Actions arise from complaints filed by Exelixis against MSN in 2019 and 2020. On October 29, 2019, Exelixis filed a complaint against MSN asserting infringement of U.S. Patent No. 8,877,776. On May 11, 2020, Exelixis filed an additional complaint against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284. In April 2022, Exelixis agreed not to assert infringement of, and MSN agreed to withdraw its validity challenges to, U.S. Patent No. 8,497,284. A trial was held in the Delaware District Court in May 2022 to adjudicate the 2019/2020 MSN ANDA Actions, and a judgment is pending. Exelixis is seeking, among other remedies, equitable relief enjoining MSN from infringing U.S. Patent Nos. 8,877,776 and 7,579,473, as well as an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of the patents at issue in the 2019/2020 MSN ANDA Actions, the latest of which expires on October 8, 2030.

The February 2022 MSN ANDA Action arises from a complaint filed by Exelixis against MSN in February 2022, asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015. The February 2022 MSN ANDA Action is scheduled for a bench trial in May 2023. Exelixis is seeking, among other remedies, equitable relief enjoining MSN from infringing U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, as well as an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of the patents at issue in the February 2022 MSN ANDA Action, which expire on January 15, 2030.

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.

July 19, 2022

Date

/s/ JEFFREY J. HESSEKIEL

Jeffrey J. Hessekiel

Executive Vice President, General Counsel and Secretary