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): February 1, 2024

FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-32295
(Commission File Number)

British Columbia, Canada (State or other jurisdiction of incorporation)	**20-0442384** (I.R.S. Employer Identification No.)
PO Box 13628, 68 TW Alexander Drive, Research Triangle Park, NC (Address of principal executive offices)	**27709** (Zip Code)

Registrant's telephone number, including area code: (919) 636-4530

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:

☐ 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 of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common shares, no par value	FENC	Nasdaq Capital Market

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 February 1, 2024, Fennec Pharmaceuticals Inc. issued a news release announcing the U.S. Food and Drug Administration (FDA) has issued a public reminder to healthcare providers that PEDMARKÒ (sodium thiosulfate injection) is not substitutable with other sodium thiosulfate products as explicitly directed in its prescribing label. PEDMARK is the first and only FDA approved therapy indicated to reduce the risk of ototoxicity (e.g., permanent hearing loss) associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. A copy of the news release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including the exhibit attached hereto, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
Exhibit 99.1	Press Release dated February 1, 2024

SIGNATURE

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.

FENNEC PHARMACEUTICALS INC.

Date February 1, 2024

By: /s/ Robert Andrade
Robert Andrade
Chief Financial Officer

FDA Issues Reminder of Non-Substitution of PEDMARK® (sodium thiosulfate injection) for Pediatric Patients Receiving Cisplatin

RESEARCH TRIANGLE PARK, N.C., February 1, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has issued a public reminder to healthcare providers that PEDMARK® (sodium thiosulfate injection) is not substitutable with other sodium thiosulfate products as explicitly directed in its prescribing label. PEDMARK is the first and only FDA approved therapy indicated to reduce the risk of ototoxicity (e.g., permanent hearing loss) associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

The FDA stated in the public communication that it is aware that some providers may be preparing other sodium thiosulfate (STS) products for patient use in place of PEDMARK, including diluting STS products approved for other uses to match the strength of PEDMARK. The FDA reminded health care providers that as stated in PEDMARK's prescribing information, PEDMARK is not substitutable with other sodium thiosulfate products. The FDA stated that such substitutions pose potential health risks, including:

- Potassium chloride exposure which, at high doses, can lead to increased risk of acute cardiac events and other serious adverse reactions. Potassium chloride is not present in PEDMARK.
- Overexposure to boric acid (a boron compound), can cause health risks including headache, hypothermia, restlessness, weariness, renal injury, dermatitis, alopecia, anorexia and indigestion. Although PEDMARK also contains boric acid, it is at a lower concentration than other STS products.
- Overexposure to sodium nitrite, which can lead to health risks including methemoglobinemia. Sodium nitrite is co-packaged with sodium thiosulfate as a separate vial in some products; it is not present in PEDMARK.

The public communication was issued by the FDA's Professional Affairs and Stakeholder Engagement Staff within the Center for Drug Evaluation and Research, Office of Communications. The FDA encourages those with any questions to contact FDAOncology@fda.hhs.gov.

About Fennec Pharmaceuticals
Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® and Pedmarqsi to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission Marketing Authorization in June 2023 for Pedmarqsi. PEDMARK has received Orphan Drug Exclusivity in the U.S. for seven years of market protection and Pedmarqsi has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. Fennec has a license agreement with Oregon Health and Science University (OHSU) for exclusive worldwide license rights to intellectual property directed to sodium thiosulfate and its use for chemoprotection, including the reduction of risk of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com.

For further information, please contact:

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