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): May 28, 2021

FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-32295
(Commission File Number)

British Columbia, Canada	**20-0442384**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)
PO Box 13628, 68 TW Alexander Drive, Research Triangle Park, NC	**27709**
(Address of principal executive offices)	(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 May 28, 2021, Fennec Pharmaceuticals Inc. issued a news release announcing it has completed its resubmission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for PEDMARK™ (sodium thiosulfate anhydrous injection) for intravenous use. 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 May 28, 2021

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 May 28, 2021

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

Exhibit 99.1

FENNEC PHARMACEUTICALS RESUBMITS NEW DRUG APPLICATION TO U.S. FOOD AND DRUG ADMINISTRATION FOR PEDMARK™

~ If Approved by the FDA, PEDMARK Stands to Be the First Therapy for the Prevention of Cisplatin-Induced Hearing Loss in Children ~

***Research Triangle Park, NC,* May 28, *2021* –** Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a specialty pharmaceutical company, today announced the resubmission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for PEDMARK™ (a unique formulation of sodium thiosulfate) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to < 18 years of age with localized, non-metastatic, solid tumors.

The resubmission for PEDMARK follows receipt of final minutes from a Type A meeting with the FDA. Importantly, the Complete Response Letter (CRL) received on August 10, 2020 referred to deficiencies with the facility of the drug product manufacturer; no clinical safety or efficacy issues were identified and there was no requirement for further clinical data.

"We are pleased to have resubmitted the NDA for PEDMARK™ and look forward to working with the FDA through the review process," said Rosty Raykov, Chief Executive Officer of Fennec Pharmaceuticals, Inc. "We remain committed to reducing the risk of life-long hearing loss for children receiving cisplatin chemotherapy. If approved, PEDMARK stands to be the first FDA approved therapy to reduce the risk of cisplatin induced ototoxicity in pediatric patients."

About PEDMARK™

Cisplatin and other platinum compounds are essential chemotherapeutic agents for many pediatric malignancies. Unfortunately, platinum-based therapies cause ototoxicity, or hearing loss, which is permanent, irreversible, and particularly harmful to the survivors of pediatric cancer.

In the U.S. and Europe, it is estimated that, annually, over 10,000 children may receive platinum-based chemotherapy. The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult, and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. Infants and young children that suffer ototoxicity at critical stages of development lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

PEDMARK has been studied by co-operative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, The Clinical Oncology Group Protocol ACCL0431 and SIOPEL 6. Both studies have been completed. The COG ACCL0431 protocol enrolled childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, medulloblastoma, and other solid tumors. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

The Marketing Authorization Application (MAA) for sodium thiosulfate (tradename PEDMARQSI) is currently under evaluation by the European Medicines Agency (EMA). PEDMARK received Breakthrough Therapy and Fast Track Designation from the FDA in March 2018.

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development of PEDMARK™ for the prevention of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK has received Orphan Drug Designation in the U.S. for this potential use. 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 prevention of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include the Company's expectations regarding its interactions and communications with the FDA, including the Company's expectations and goals respecting the resolution the issues raised in the CRL and the Company's plans to address them, and the anticipated timing of the Company's finalization and filing of an NDA resubmission for PEDMARK. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such risks and uncertainties relating to the Company's reliance on third party manufacturing, the risk that unforeseen factors may delay the resubmission of the NDA, the risks of delays in or failure to obtain FDA approval of PEDMARK, the risks relating to the Company's and its manufacturer's ability to adequately address the concerns identified in the CRL, the risk that the resubmission of the NDA to the FDA will not be satisfactory, that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2020. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

For further information, please contact:

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