

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): June 22, 2021

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 June 22, 2021, Fennec Pharmaceuticals Inc. issued a news release announcing that the U.S. Food and Drug Administration has accepted for filing the resubmission for the company's New Drug Application for PEDMARK™ (a unique formulation of sodium thiosulfate). The Prescription Drug User Fee Act (PDUFA) target action date has been set for November 27, 2021. PEDMARK is an investigational drug for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to <18 years of age 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 June 22, 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 June 22, 2021

By: /s/ Robert Andrade

Robert Andrade

Chief Financial Officer



FENNEC PHARMACEUTICALS ANNOUNCES FDA ACCEPTANCE OF NEW DRUG APPLICATION RESUBMISSION FOR PEDMARK™

~ Prescription Drug User Fee Act (PDUFA) Target Action Date Set for November 27, 2021 ~

~ NDA Resubmission for PEDMARK for the Prevention of Cisplatin-Induced Ototoxicity for Pediatric Patients with Localized, Non-Metastatic Solid Tumors ~

~ 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, June 22, 2021 – Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the resubmission of its New Drug Application (NDA) 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 Prescription Drug User Fee Act (PDUFA) target action date has been set for November 27, 2021.

“We are pleased that the FDA has accepted our PEDMARK™ resubmission,” said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals, Inc. “We look forward to working closely with the FDA through the review process. We are committed to bringing this treatment to children receiving cisplatin chemotherapy, an area of high unmet medical need. If approved, PEDMARK™ stands to be the first FDA approved therapy to reduce the risk of cisplatin induced ototoxicity in pediatric patients.”

PEDMARK has been granted both Fast Track Designation and Breakthrough Therapy Designation by the FDA. 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.

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 (tradenname 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 NDA resubmission for PEDMARK™. Obtaining Fast Track Designation and Breakthrough Therapy Designation by the FDA is no guarantee that the FDA will approve the NDA resubmission of 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 the risk that unforeseen factors may result in delays in or failure to obtain FDA approval of PEDMARK, the risks and uncertainties relating to the Company’s reliance on third party manufacturing, the risks that the Company’s NDA resubmission does not adequately address the concerns identified in the CRL previously provided by the FDA, the risk that the NDA resubmission 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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