

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): April 13, 2020

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 April 13, 2020, Fennec Pharmaceuticals Inc. issued a news release announcing that the U.S. Food and Drug Administration has accepted for filing and granted Priority Review for the company's New Drug Application for PEDMARK™ (a unique formulation of sodium thiosulfate). 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 April 13, 2020](#)

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 April 13, 2020

By: /s/ Robert Andrade

Robert Andrade
Chief Financial Officer



FENNEC PHARMACEUTICALS ANNOUNCES FDA FILING ACCEPTANCE AND PRIORITY REVIEW OF NEW DRUG APPLICATION FOR PEDMARK™

~ Potential for PEDMARK to be the First Product for the Prevention of Cisplatin-Induced Hearing Loss in Children ~

~ FDA Grants Priority Review and Sets a Prescription Drug User Fee Act (PDUFA) Target Action Date of August 10, 2020 ~

Research Triangle Park, NC, April 13, 2020 – Fennec Pharmaceuticals Inc. (Nasdaq: FENC; TSX: FRX), a specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted Priority Review for the company's New Drug Application (NDA) for PEDMARK™ (a unique formulation of sodium thiosulfate). 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.

"The FDA filing acceptance of our NDA and granting of Priority Review represents a significant milestone in the development of PEDMARK and we look forward to working closely with the Agency during this review process," said Rosty Raykov, chief executive officer of Fennec.

The FDA grants Priority Review to applications for medicines that treat a serious condition, and, if approved, would demonstrate the potential to be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Priority Review designation shortens the review period from the standard ten months to six months from the submission of the NDA. The FDA set a Prescription Drug User Fee Act (PDUFA) target action date of August 10, 2020 for the completion of FDA's review.

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 cooperative 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 one of five childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, and medulloblastoma. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

The FDA has accepted for filing the Company's New Drug Application (NDA) for PEDMARK™ and has granted Priority Review. The Marketing Authorization Application (MAA) for sodium thiosulfate (tradenname to be determined) is currently under evaluation by the European Medicines Agency (EMA). PEDMARK has received Breakthrough Therapy and Fast Track Designation by 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 STS 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. 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 as 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, that regulatory and guideline developments may change, scientific data 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, 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 product will not be as large as expected, the Company's product 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, 2019. Fennec Pharmaceuticals, Inc. 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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