

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 11, 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 February 11, 2020, Fennec Pharmaceuticals Inc. issued a news release announcing it has completed its rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for PEDMARKTM (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 February 11, 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 February 11, 2020

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



FENNEC PHARMACEUTICALS COMPLETES ROLLING SUBMISSION OF NEW DRUG APPLICATION (NDA) TO U.S. FOOD AND DRUG ADMINISTRATION FOR PEDMARKTM AND ALSO SUBMITS MARKETING AUTHORIZATION APPLICATION (MAA) TO EUROPEAN MEDICINES AGENCY

PEDMARKTM is Being Developed for Prevention of Cisplatin-Induced Hearing Loss in Children

Research Triangle Park, NC, Feb. 11, 2020 – Fennec Pharmaceuticals Inc. (Nasdaq:FENC; TSX: FRX), a specialty pharmaceutical company, today announced it has completed its rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for PEDMARKTM (a unique formulation of sodium thiosulfate) for intravenous use and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for sodium thiosulfate (tradename to be determined). The PEDMARKTM indication requested is for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to < 18 years of age with localized, non-metastatic, solid tumors.

Fennec’s PEDMARK regulatory submissions follow: a pre-NDA meeting with the FDA in December 2018 after which Fennec initiated a rolling NDA; and pre-submission meetings with the EMA and an approved pediatric investigation plan (PIP). Both applications are based upon clinical results from two pivotal Phase 3 clinical trials:

- SIOPEL 6 conducted by the International Childhood Liver Tumor Strategy Group (SIOPEL) with results published in the New England Journal of Medicine in June 2018

and

- ACCL0431 conducted by the Children’s Oncology Group (COG) with results published in Lancet Oncology in 2016.

“At Fennec, we are dedicated to the development of PEDMARK for the prevention of ototoxicity in children. The completion of these regulatory submissions to the FDA and EMA are the culmination of many years of hard work, bringing us one step closer to achieving our mission,” said Rosty Raykov, chief executive officer of Fennec. “Fennec would like to thank the many parents, children and investigators who participated in the clinical trials, as well as our dedicated employees who helped us reach this important milestone. We are well underway with commercialization readiness activities to support the potential launch of PEDMARK and our transition to becoming a commercial-stage organization.”

¹ PEDMARK is US proposed tradename. European tradename is under evaluation.

The FDA has a 60-day review period to determine whether the PEDMARK NDA is acceptable for filing. PEDMARK has been granted Orphan Drug, Breakthrough Therapy, and Fast Track designations from the FDA. If PEDMARK is granted a priority review, the Prescription Drug User Fee Act (PDUFA) action date is expected in the third quarter of 2020.

About PEDMARK™ (Sodium Thiosulfate (STS))

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 is particularly harmful to the survivors of pediatric cancer.

In the U.S. and Europe, it is estimated annually that 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.

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. PEDMARK received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018. Further, PEDMARK has received Orphan Drug Designation in the U.S. for this setting. 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 that regulatory and guideline developments may change, scientific data or the Company's new drug applications may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, commercialization execution, 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 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, 2018. Fennec Pharmaceuticals, Inc. disclaims any obligation to update these forward-looking statements except as required by law.

The scientific information discussed in this news release related to PEDMARK is preliminary and investigative. Such product candidates are not approved by the FDA, EMA, Health Canada or other regulatory bodies and no conclusions can or should be drawn regarding the safety or effectiveness of such product candidate.

For further information, please contact:

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