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): March 27, 2018

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))

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 March 27, 2018, Fennec Pharmaceuticals Inc. ("Fennec") announced the U.S. Food and Drug Administration (FDA) has granted PEDMARK™ (a unique formulation of sodium thiosulfate) Breakthrough Therapy designation for the prevention of cisplatin-related ototoxicity in pediatric patients with standard risk hepatoblastoma (SR-HB).

On March 27, 2018, Fennec issued a press release announcing this news as described above. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
Exhibit 99.1	Press Release dated March 27, 2018

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 March 28, 2018

By: /s/ Rostislav Raykov
Rostislav Raykov
Chief Executive Officer

Exhibit 99.1

FENNEC PHARMACEUTICALS RECEIVES BREAKTHROUGH THERAPY DESIGNATION BY FDA FOR PEDMARK™

Research Triangle Park, NC, March 27, 2018 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted PEDMARK™ (a unique formulation of sodium thiosulfate) Breakthrough Therapy designation for prevention of cisplatin-related ototoxicity in pediatric patients with standard risk hepatoblastoma (SR-HB).

"The decision by the FDA to grant PEDMARK the first Breakthrough Therapy designation for the prevention of cisplatin ototoxicity reflects a recognition of the promising efficacy and safety data generated from SIOPEL 6 and COG ACCL0431 studies. We believe the recent receipt of Fast Track designation, and today, Breakthrough Therapy designation highlights the current lack of safe and effective treatments and overwhelming need to address this serious condition," said Rosty Raykov, President and Chief Executive Officer of Fennec. "This designation is another significant milestone for the advancement of PEDMARK™, as we work closely with the Agency to expedite the NDA filing."

According to FDA, Breakthrough Therapy designation is given when preliminary clinical evidence has been provided to show that a treatment effect may represent substantial improvement over available therapies for the treatment of a serious condition. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. Additional information is available under the FDA guidance for Industry Expedited Programs for Serious Conditions - Drugs and Biologics: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

About PEDMARK™ (Sodium Thiosulfate (STS))
Cisplatin and other platinum compounds are essential chemotherapeutic components for many pediatric malignancies. Unfortunately, platinum-based therapies cause ototoxicity in many patients, and are particularly harmful to the survivors of pediatric cancer.

In the U.S. and Europe there is estimated that over 10,000 children may receive platinum based chemotherapy. The incidence of hearing loss in these children 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 at critical stages of development lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

STS 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 are 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 Sodium Thiosulfate (STS) for the prevention of platinum-induced ototoxicity in pediatric patients. STS has received Orphan Drug Designation in the US in this setting. For more information, please visit www.fennecpharma.com.

For further information, please contact:

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