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): November 30, 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 November 30, 2021, Fennec Pharmaceuticals Inc. issued a news release announcing that the Company has received a Complete Response Letter from the U.S. Food and Drug Administration for its New Drug Application for PEDMARK™ (a unique formulation of sodium thiosulfate). PEDMARK is an investigational drug for reducing the risk 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 November 30, 2021
Exhibit 104	Cover Page Interactive Data File (formatted as Inline XBRL)

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 November 30, 2021

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

Exhibit 99.1

Fennec Pharmaceuticals Receives Complete Response Letter from the FDA for its New Drug Application for PEDMARK™ to Prevent Ototoxicity Associated with Cisplatin in Pediatric Patients with Localized, Non-Metastatic, Solid Tumors

RESEARCH TRIANGLE PARK, N.C., November 30, 2021 – Fennec Pharmaceuticals Inc., a specialty pharmaceutical company, today announced that it received a Complete Response Letter (CRL) on November 29, 2021 from the U.S. Food and Drug Administration (FDA), after the PDUFA target action date of November 27, 2021, regarding its New Drug Application (NDA) for PEDMARK™ (a unique formulation of sodium thiosulfate), for intravenous administration for the prevention of ototoxicity associated with cisplatin chemotherapy in pediatric patients ≥ 1 month to 18 years of age with localized, non-metastatic, solid tumors.

The CRL was issued as a result of identified manufacturing deficiencies which need to be satisfactorily resolved before the Pedmark NDA can be approved. Fennec plans to request a Type A meeting with the FDA to discuss these deficiencies and other matters described in the CRL, as well as the steps required for the resubmission of the NDA for PEDMARK™.

“We are steadfast in our commitment to reducing the risk of life-long hearing loss for children and young adults receiving cisplatin chemotherapy who currently have no approved therapies for this devastating condition,” said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. “We will work closely with our current manufacturer as well as the FDA to fully address the issues raised in the letter. In addition, we continue to advance our second drug product manufacturing facility.”

As of September 30, 2021, Fennec has existing cash and cash equivalents, which totaled approximately $24 million.

About PEDMARK™ (A unique formulation of 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 that, annually, more than 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 type of 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 Marketing Authorization Application (MAA) for sodium thiosulfate (tradename PEDMARQSI) 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 setting. Fennec has a license agreement with Oregon Health and Science University 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. These forward-looking statements include the Company's expectations regarding its interactions and communications with the FDA, including its expectation to discuss with the FDA the issues raised in the CRL and the Company's plans to address them. 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 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, Fennec's reliance on third party manufacturing, 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 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. 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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