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): September 21, 2022

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 September 21, 2022, Fennec Pharmaceuticals Inc. issued a news release announcing the U.S. Food and Drug Administration has approved PEDMARK® (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older 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 September 21, 2022
Exhibit 104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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 September 21, 2022

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

Exhibit 99.1

Fennec Pharmaceuticals Announces FDA Approval of PEDMARK® (Sodium Thiosulfate Injection)

~ PEDMARK® is the First and Only FDA-Approved Therapy Indicated to Reduce the Risk of Ototoxicity Associated with Cisplatin in Pediatric Patients with Localized, Non-Metastatic Solid Tumors ~

RESEARCH TRIANGLE PARK, N.C., Sept. 21, 2022 (GLOBE NEWSWIRE) -- Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved PEDMARK® (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. This approval makes PEDMARK the first and only treatment approved by the FDA in this area of significant unmet medical need.

“The FDA approval of PEDMARK represents an important breakthrough for pediatric patients with localized, non-metastatic solid tumors at risk for cisplatin-induced hearing loss. Cisplatin is a critical, standard of care agent, used in the treatment of pediatric cancers; however, even though effective, it could be harmful to children, frequently causing permanent and irreversible bilateral hearing loss. With PEDMARK, physicians now have an approved treatment option to reduce the risk of cisplatin-induced hearing loss in pediatric patients,” said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. “We would like to thank the patients, their families, physicians, investigators, employees, consultants and the entire research team at Oregon Health and Science University, who have contributed to the development of PEDMARK.”

The FDA approval of PEDMARK was based upon safety and efficacy data from two pivotal open-label, randomized Phase 3 trials (SIOPEL 6 and COG ACCL0431), which compared PEDMARK plus cisplatin-based regimen to cisplatin-based regimens alone for the reduction of cisplatin-induced hearing loss in pediatric patients. In both studies, the incidence of hearing loss was consistently and significantly lower in the PEDMARK plus cisplatin arm compared with the cisplatin alone arm [21.4% vs. 73.3% ($p = 0.005$) and 32.7% vs. 63% ($p = 0.002$) with hearing loss in COG ACCLO431 and SIOPEL6, respectively]. The most common adverse reactions (≥ 25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 are vomiting, infection, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 is hypokalemia.

“Historically, there have been no approved treatments for preventing cisplatin-induced hearing loss. As a physician focused in pediatric cancer for many years, and a primary investigator in the pivotal PEDMARK Phase 3 Clinical Oncology Group (COG) trial, the FDA approval of PEDMARK addresses an enormous unmet need and for many children and young adults, has the potential to greatly improve everyday activities for these patients,” said David R. Freyer, DO, MS, Primary Investigator, COG ACCL0431, and Director of the Survivorship & Supportive Care Program, Cancer and Blood Disease Institute, Children’s Hospital Los Angeles.

Advances in chemotherapy-based treatment approaches for pediatric patients with localized, solid tumors have improved, resulting in an 85 percent or higher five-year survival rate for these patients[2]. However, use of platinum-based chemotherapy, still the treatment of choice in many cases, can be toxic to the ears and cisplatin treatment frequently causes permanent and irreversible bilateral (affecting both ears) hearing loss. Permanent hearing loss can be seen in approximately 60 percent of children treated with cisplatin and can be as high as 90 percent.[1,2] Until now, interventions with management strategies such as cochlear implants and hearing aids only occurred after hearing loss had been detected and these interventions do not return normal hearing.[3]

“Hearing loss can have a profound impact on a person’s life, especially in children who are critically dependent upon normal hearing for cognitive, psychosocial, and speech development,” said Penelope "Peppy" R. Brock, M.D., Ph.D., of Great Ormond Street Hospital in London and International Chair of the SIOPEL 6 trial. “Incorporating PEDMARK® into current treatment strategies with the goal to preserve hearing in children and young adults without reducing the effectiveness of their cisplatin treatment – is a welcome step towards helping to improve long-term outcomes for these patients.”

For more information about product availability and patient support, please contact the Fennec HEARS™ program at 1-833-7PEDMARK (1-833-773-3627).

The FDA granted this application Priority Review designation. PEDMARK also received Orphan Drug designation by the FDA in 2004.

The Marketing Authorization Application (MAA) for sodium thiosulfate (tradename PEDMARQSI) is currently under evaluation by the European Medicines Agency (EMA).

About Cisplatin-Induced Ototoxicity
Cisplatin and other platinum compounds are essential chemotherapeutic agents for the treatment of many pediatric malignancies. Unfortunately, platinum-based therapies can cause ototoxicity, or hearing loss, which is permanent, irreversible, and particularly harmful to the survivors of pediatric cancer.[4]

The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids or cochlear implants, which can be helpful for some, but do not reverse the hearing loss and can be costly over time.[5] Infants and young children that are affected by ototoxicity at critical stages of development lack speech and language development and literacy, and older children and adolescents often lack social-emotional development and educational achievement.[6]

About PEDMARK® (sodium thiosulfate injection)
PEDMARK® is the first and only U.S. Food and Drug Administration (FDA) approved therapy indicated to reduce the risk of ototoxicity associated with cisplatin treatment in pediatric patients with localized, non-metastatic, solid tumors. It is a unique formulation of sodium thiosulfate in single-dose, ready-to-use vials for intravenous use in pediatric patients.[7] PEDMARK® is also the only therapeutic agent with proven efficacy and safety data with an established dosing paradigm, across two open-label, randomized Phase 3 clinical studies, the Clinical Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

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 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.

Indications and Usage
PEDMARK® (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Limitations of Use
The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Important Safety Information
PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.

Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.

Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m^2.

Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.

The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full Prescribing Information for PEDMARK® at: **https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212937s000lbl.pdf.**

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® for the prevention of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and has received Orphan Drug Designation in the U.S. 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 statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use. 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 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, 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, 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.

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[1] Langer T, Zehnhoff-Dinnesen A, Radtke S, et al. Understanding Platinum-Induced Ototoxicity. *Trends in Pharmacological Sciences*. August 2013, Vol. 34, No. 8:458-469.

[2] American Cancer Society. Key Statistics for Childhood Cancers. Last Revised: January 12, 2022. https://www.cancer.org/cancer/cancer-in-children/key-statistics.html

[3] Paken J, Govender C. Pillay M, et al. Cisplatin-Associated Ototoxicity: A Review for The Health Professional. Journal of Toxicology. Vol. 2016:1-13.

[4] Rybak L. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. *Current Opinion in Otolaryngology & Head and Neck Surgery*. 2007, Vol. 15: 364 - 369

[5] Landier W. Ototoxicity and Cancer Therapy. *Cancer*. June 2016 Vol. 122, No.11: 1647-1658.

[6] Bass JK, Knight KR, Yock TI, et al. Evaluation and Management of Hearing Loss in Survivors of Childhood and Adolescent Cancers: A Report from the Children's Oncology Group. *Pediatric Blood & Cancer*. 2016 Jul;63(7):1152-1162.

[7] PEDMARK® Prescribing Information. 11 Description.