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 17, 2026

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 17, 2026, Fennec Pharmaceuticals Inc. (the "Company") announced positive results from the investigator-initiated Phase 2 STS-J01 clinical study of PEDMARK® in Japan, which met its primary endpoint and demonstrated significant hearing protection without evidence of interference with cisplatin antitumor activity.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 8.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor incorporated by reference into any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
Exhibit 99.1	Press Release dated September 17, 2026
Exhibit 104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the 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 17, 2026

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

FENNEC PHARMACEUTICALS ANNOUNCES ORAL PRESENTATION OF DETAILED RESULTS FROM INVESTIGATOR-INITIATED PHASE 2 STS-J01 CLINICAL STUDY OF PEDMARK® IN JAPAN AT SIOP 2026

~ Primary Endpoint Met: American Speech-Language-Hearing Association (ASHA)-Defined Hearing Loss Occurred in 24.0% of Patients Versus the Prespecified Historical Benchmark of 56.4% (P=0.001) ~

~ 84% of Patients Had Grade 0 Hearing Loss by Brock Criteria; No Grade 3 or Grade 4 Hearing Loss Was Observed ~

~ Objective Responses Observed in 23 of 24 Evaluable Patients (95.8%); Prospective Pharmacokinetic Analyses Provide New Mechanistic Insight Supporting the Six-Hour PEDMARK® Administration Interval for Pediatric & Adolescent and Young Adult (AYA) Patients ~

~ Building Upon the Pivotal Children's Oncology Group (COG) Protocol ACCL0431 & SIOPEL 6 Studies, STS-J01 Represents Third Study to Demonstrate that PEDMARK® Showed No Interference with Cisplatin Antitumor Activity ~

Research Triangle Park, NC, September 17, 2026 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today announced the oral presentation of detailed results from the investigator-initiated Phase 2 STS-J01 clinical trial evaluating PEDMARK® (sodium thiosulfate injection) for the reduction of cisplatin-induced ototoxicity in pediatric and adolescent and young adult (AYA) patients with non-metastatic solid tumors in Japan. The data will be presented today during the 58th Annual International Society of Pediatric Oncology (SIOP) Annual Meeting in San Antonio, TX.

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 1 month of age and older with localized, non-metastatic, solid tumors, and is also recognized by the National Comprehensive Cancer Network with a 2A endorsement for use in AYA patients.

The study enrolled 33 patients across 11 institutions in Japan, including 27 patients in the primary cohort and six in exploratory cohorts. Key study findings include:

- Among the 25 patients comprising the primary efficacy population, ASHA-defined hearing loss occurred in 24.0% (6/25), significantly lower than the prespecified historical benchmark of 56.4% (P=0.001).
- Nineteen of 25 patients (76.0%) remained free of ASHA-defined hearing loss. By Brock criteria, 84.0% of patients had Grade 0 hearing loss, and no patient experienced Grade 3 or Grade 4 hearing loss.
- Objective tumor responses were observed in 23 of 24 evaluable patients (95.8%), providing reassuring clinical context for delayed PEDMARK® administration six hours following cisplatin.
- Prospective pharmacokinetic analyses further characterized the interaction between PEDMARK® and cisplatin-derived platinum and provide mechanistic support for the six-hour administration strategy for pediatric and adolescent and young adult (AYA) patients.

"The clinical and pharmacologic findings of STS-J01 are compelling. We observed a significant reduction in hearing loss, with no Grade 3 or Grade 4 hearing loss by Brock criteria, alongside a 95.8% objective response rate in evaluable patients. The prospective pharmacokinetic analyses further provide important mechanistic insight into why the six-hour interval matters, supporting a model in which PEDMARK® acts on residual circulating and exchangeable platinum after cisplatin has had time to distribute and initiate its antitumor activity. Together, these findings add an important independent body of evidence supporting the clinical rationale for delayed PEDMARK® administration," said Pierre S. Sayad, PhD, M.S., chief medical officer of Fennec Pharmaceuticals.

The safety profile was consistent with the known tolerability profile of PEDMARK® and the expected toxicities of cisplatin-containing chemotherapy. No serious adverse event was attributed to PEDMARK®, and no Grade 4 PEDMARK®-related toxicity was observed.

"For patients navigating cancer in Japan, the ability to successfully treat their tumors while preserving hearing can have a profound impact on their lives long after treatment ends. Cisplatin remains an important and effective treatment, but the risk of permanent hearing

loss represents a significant unmet need, particularly for children and young people who may live with its consequences for the rest of their lives," said Eiso Hiyama, M.D., PhD, lead investigator and professor in the Department of Pediatric Surgery at Hiroshima University Hospital in Hiroshima, Japan. "The results from STS-J01 are encouraging because they demonstrate significant hearing protection and provide reassuring clinical context regarding antitumor activity with delayed PEDMARK® administration. We believe that these results provide further support and confidence in PEDMARK® for healthcare professionals."

Fennec is pursuing registration in Japan and is currently exploring partnering or licensing opportunities for PEDMARK®.

About the STS-J01 Study
STS-J01 is a Phase 2, investigator-initiated, open-label, single-arm clinical trial designed to evaluate PEDMARK® for the prevention of cisplatin-induced ototoxicity. The study enrolled 33 patients in two cohorts: 27 children ages 3-18 years (primary cohort), and 6 patients in exploratory cohorts, all with localized-stage solid tumors, including neuroblastoma, hepatoblastoma, germ cell tumors, bone and soft tissue sarcomas, medulloblastoma, and atypical teratoid rhabdoid tumors. Patients received PEDMARK® intravenously six hours after cisplatin infusion, with dosing adjusted by body weight. The primary endpoint was the incidence of hearing impairment at the end of treatment in the 3- to 18-year-old cohort, assessed according to American Speech-Language-Hearing Association (ASHA) criteria. Secondary endpoints included safety, antitumor efficacy, pharmacokinetics, and incidence of hearing loss as measured by Brock grading. Exploratory measures included longitudinal audiometric follow-up and validation of surrogate hearing tests.

About Cisplatin-Induced Ototoxicity
Cisplatin and other platinum-based chemotherapies are widely used to treat solid tumors and have been vital in improving survival rates. Unfortunately, these life-saving treatments often result in permanent, irreversible hearing loss, also known as ototoxicity.[i]

Hearing loss from cisplatin treatment is not rare. Studies show that between 60-90% of patients treated with cisplatin may develop hearing loss, depending upon the dose and duration of chemotherapy.[ii] Many of those treated with cisplatin will 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.[iii] Treatment-induced hearing loss can reduce quality of survivorship as it impacts many aspects of life, such as speech and language skills, academic performance, social-emotional development, career potential and the ability to live independently.[iv,v] While audiologic monitoring is recommended to help manage ototoxicity, it is currently underutilized in certain cancer patient populations.

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 1 month of age and older 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. PEDMARK is also the first and only therapeutic agent with proven efficacy and safety data with an established dosing regimen, across two open-label, randomized Phase 3 clinical studies, the Children's Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

Additionally, PEDMARK® is recommended for the adolescent and young adult (AYA) population by the National Comprehensive Cancer Network, or NCCN, with a 2A endorsement.

Approximately 500,000 patients in the U.S. are diagnosed annually with cancers that could be treated with a platinum-based chemotherapy.[vi,vii] The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of those treated will require lifelong hearing aids. Until the FDA approval of PEDMARK, there were no preventative agents for this hearing loss. Patients with hearing loss resulting from cancer treatment have a statistically significant worse quality of life compared with peers who have no hearing loss.[viii,ix]

PEDMARK has been studied by co-operative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, COG ACCL0431 and SIOPEL 6. Both studies have been completed. The COG ACCL0431 protocol enrolled childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, medulloblastoma, and other solid tumors. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

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 levels 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 SIOPEL 6 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: www.PEDMARK.com.

About Fennec Pharmaceuticals
Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company committed to the fight against ototoxicity in cancer patients who receive cisplatin-based chemotherapy. Fennec is focused on the commercialization of PEDMARK® to reduce the risk of platinum-induced ototoxicity in cancer patients. PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and United Kingdom (U.K.) approval in October 2023 under the brand name PEDMARQSIÒ.

In March 2024, Fennec entered into an exclusive licensing agreement under which Norgine Pharmaceuticals Ltd., a leading European specialist pharmaceutical company, will commercialize PEDMARQSI® in Europe, U.K., Australia and New Zealand. PEDMARQSI is now commercially available in multiple countries.

PEDMARK has received Orphan Drug Exclusivity in the U.S. and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. Further, Fennec has patents providing protection for PEDMARK until 2039 in both the U.S. and internationally.

For more information, please visit www.fennecpharma.com and follow on LinkedIn.

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®/PEDMARQSI®, the market opportunity for and market impact of PEDMARK®/ PEDMARQSI®, its potential impact on patients and anticipated benefits associated with its use, future commercial and regulatory milestone and royalty payments from Norgine, potential regional partnering or licensing opportunities for PEDMARK®/PEDMARQSI®, and potential access to further funding after the date of this release. 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, our ability to obtain necessary capital when needed on acceptable terms or at all, 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, 2025. 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:

Investors:
Robert Andrade
Chief Financial Officer
Fennec Pharmaceuticals Inc.
+1 919-246-5299

Corporate and Media:
Lindsay Rocco
Elixir Health Public Relations
+1 862-596-1304
lrocco@elixirhealthpr.com

---

[i] Sheth S et al. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. *Frontiers in Cellular Neuroscience*. 2017, Vol. 11.
[ii] Langer T, am Zehnhoff-Dinnesen A, Radtke S, Meitert J, Zolk O. Understanding platinum-induced ototoxicity. *Trends Pharmacol Sci*. 2013;34(8):458-469
[iii] Landier W. Ototoxicity and Cancer Therapy. *Cancer*. June 2016 Vol. 122, No.11: 1647-1658.
[iv] Clemens E, van den Heuvel-Eibrink MM, Mulder RL, et al. Recommendations for ototoxicity surveillance for childhood, adolescent, and young adult cancer survivors: a report from the International Late Effects of Childhood Cancer Guideline Harmonization Group in collaboration with the PanCare Consortium. *Lancet Oncol*. 2019;20(1):e29-e41
[v] Bass JK, Knight KR, Yock TI, Chang KW, Cipkala D, Grewal SS. Evaluation and management of hearing loss in survivors of childhood and adolescent cancers: a report from the children's oncology group. *Pediatr Blood Cancer*. 2016;63(7):1152-1162.
[vi] Chattaraj A et al. Cisplatin-Induced Ototoxicity: A Concise Review of the Burden, Prevention, and Interception Strategies. *JCO Oncol Pract*. 2023;19
[vii] Freyer DR et al. Effects of sodium thiosulfate versus observation on development of cisplatin-induced hearing loss in children with cancer (ACCL0431): a multicentre, randomised, controlled, open-label, phase 3 trial. *Lancet Oncol*. 2017;18(1):63-74.
[viii] Rajput K, Edwards L, Brock P, Abiodun A, Simpkin P, Al-Malky G. Ototoxicity-induced hearing loss and quality of life in survivors of paediatric cancer. *Int J Pediatr Otorhinolaryngol*. 2020;138:110401. doi:10.1016/j.ijporl.2020.110401
[ix] Bass JK, Knight KR, Yock TI, Chang KW, Cipkala D, Grewal SS. Evaluation and management of hearing loss in survivors of childhood and adolescent cancers: a report from the children's oncology group. Pediatr Blood Cancer. 2016;63(7):1152-1162.