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): October 14, 2017

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 October 14, 2017, Fennec Pharmaceuticals Inc. ("Fennec") announced the results of the SIOPEL 6 study on PEDMARK™ (sodium thiosulfate) at the 49th congress of the international society of pediatric oncology (SIOP) 2017 meeting. The SIOPEL 6 abstract was presented during the late breaker session on Saturday, October 14, 2017 at SIOP 2017 in Washington, DC.

On October 16, 2017, Fennec issued a press release discussing its October 14, 2017 presentation as SIOP 2017 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 October 16, 2017

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 October 16, 2017

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

Exhibit 99.1

FENNEC ANNOUNCES POSITIVE RESULTS FROM PHASE 3 SIOPEL 6 STUDY ON PEDMARK™ (sodium thiosulfate) PRESENTED AT THE 49TH CONGRESS OF THE INTERNATIONAL SOCIETY OF PEDIATRIC ONCOLOGY (SIOP) 2017 MEETING

- **Study met primary endpoint (p=0.0033)**
- **Significant reduction in cisplatin induced hearing loss without any evidence of tumour protection in patients with Standard Risk Hepatoblastoma (SR-HB)**
- **Company plans to pursue regulatory approvals with FDA and EMA**

Research Triangle Park, NC, October 16, 2017– Fennec Pharmaceuticals Inc. (NASDAQ: FENC, TSX: FRX), a specialty pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate (STS)) for the prevention of platinum-induced ototoxicity in pediatric patients, announced today data from its Phase 3 SIOPEL 6 study presented during the late breaker session on Saturday, October 14, 2017 at SIOP 2017 in Washington, DC.

Top Line Efficacy Data

The SIOPEL 6 study met its primary endpoint. The study demonstrated that the addition of STS significantly reduces the incidence of cisplatin-induced hearing loss without any evidence of tumour protection. Among the 99 evaluable patients, hearing loss occurred in 30/45=67% treated with Cisplatin (Cis) alone and in 20/54=37.0% treated with Cis+STS, corresponding to a relative risk of 0.56(P=0.0033).

Fennec plans to pursue regulatory approval for PEDMARK™ based on the data from the SIOPEL 6 study along with the proof of principle data from COG ACCL0431. STS has received Orphan Drug Designation in the US in this setting and plans to pursue European Market Exclusivity for Pediatric Use upon approval.

“I am absolutely delighted that after 30 years of research we have found a safe way to reduce ototoxicity in children receiving platinum containing chemotherapy,” said Penelope Brock, M.D., PhD, International Chair of SIOPEL. “This means that children who are cured from cancer after receiving platinum treatment can look forward to a normal healthy life, fully integrated into society. I believe this marks a new standard of care in pediatric oncology." The Company also reported top-line data for secondary endpoints Event Free Survival (EFS) and Overall Survival (OS). The combination of Cis+STS was generally well tolerated. With a follow up of 52 months, 3yr EFS is Cis 78.8% and Cis+STS 82.1%; 3yr OS is Cis 92.3% and Cis+STS 98.2%.

"We are very pleased with the results of this study," stated Rosty Raykov, CEO of Fennec. " We would like to thank all the patients and their families who participated in this trial, physicians, the entire SIOPEL 6 team, and Dr. Neuwelt and his research team at OHSU. We believe that if approved PEDMARK would be an important therapy for patients and caregivers where currently there are no treatment options.”

Safety and Tolerability

In the study, the results presented showed that treatment was well tolerated and acute toxicity similar and expected between arms. The table below presents the toxicities of the two arms:

Adverse event	Grade	CIS		CIS+STS	
		N	%	N	%
Febrile neutropenia	3	7	13.5	5	8.8
	4	-	-	-	-
Infection	3	5	9.6	6	10.5
	4	-	-	-	-
Hypomagnesemia	3	1	1.9	1	1.8
	4	-	-	-	-
Hypernatremia	3	-	-	1	1.8
	4	-	-	-	-
Vomiting	3	1	1.9	3	5.3
	4	-	-	-	-
Nausea	3	3	5.8	2	3.5
	4	-	-	-	-

SIOP 2017 Presentation

Fennec will provide access to the recording of SIOP 2017 late breaker presentation on the Company's website.

To access the archived recording, visit the Fennec website at www.fennecpharma.com.

SIOPEL 6

SIOPEL 6 is a multi-centre open label randomized phase 3 study evaluating the efficacy of STS in reducing ototoxicity in patients receiving cisplatin monotherapy for standard risk hepatoblastoma. From the beginning of 2007 to the end 2014, 52 sites from 11 countries enrolled 113 evaluable patients. The study is closed to recruitment and all protocol pre-specified IDMC safety reviews are now complete. The primary efficacy hearing endpoint analysis can be performed once patients have reached 3.5 years of age and an audiometry test can be carried out. The SIOPEL 6 study trial was designed with 80% power and a 5% significance level to detect an absolute 25% reduction in the rate of Brock grade ≥1 hearing loss with a chi-square test, from a 60% hearing loss in Cis alone arm to a 35% hearing loss in Cis+STS arm. The primary endpoint is the rate of Brock grade ≥ 1 hearing loss determined after the end of treatment at the age of ≥3.5 years by pure tone audiometry.

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 7,000 children are diagnosed with local cancers that may receive platinum-based chemotherapy. Localized cancers that receive platinum agents may have overall survival rates of greater than 80% further emphasizing the quality of life after treatment. 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 closed to recruitment. 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. COG ACCL0431 final results were published in the Lancet Oncology.

In May 2017, Fennec announced the launch of a Named Patient Program in Europe. European based Healthcare Professionals can obtain details about STS Named Patient Program by emailing clinical@fennecpharma.com.

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. Fennec has an exclusive license agreement with 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 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, 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, 2016. 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 U.S. Food and Drug Administration, Health Canada or other regulatory and no conclusions can or should be drawn regarding the safety or effectiveness of such product candidate.

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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