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): February 14, 2020

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. ☐

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common	FENC, FRX	Nasdaq, TSX

Item 2.02. Results of Operations and Financial Condition.

On February 14, 2020, Fennec Pharmaceuticals Inc. issued a news release announcing the fourth-quarter and full-year financial results for the period ended December 31, 2019. 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 February 14, 2020

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 February 14, 2020

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

FENNEC PROVIDES BUSINESS UPDATE AND ANNOUNCES FISCAL YEAR 2019 FINANCIAL RESULTS

NDA (New Drug Application) and Marketing Authorization Application (MAA) completed in February 2020

Commercial readiness activities in U.S. underway for potential launch of PEDMARK™, if approved, in the second half of 2020

Solid financial position with $13.7 million and no debt and the option to access $12.5 million in debt financing upon NDA approval of PEDMARK

Research Triangle Park, NC, Feb. 14, 2020 – 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, today reported its business update and financial results for the fiscal year ended December 31, 2019.

"Fennec made great progress in 2019 preparing for some important milestones in 2020 including the recent announcement of regulatory submissions in both the U.S. and EU for PEDMARK" said Rosty Raykov, chief executive officer of Fennec. "During the year we also made solid progress in preparing for the potential launch of PEDMARK including the hiring of a chief commercial officer and the preparation and execution of our commercial readiness plan. We look forward to a number of significant milestones throughout 2020. If PEDMARK is granted a Priority Review, the Prescription Drug User Fee Act (PDUFA) action date is expected in the third quarter of 2020."

Financial Results for the Fourth Quarter 2019

- **Cash Position** - Cash and cash equivalents were $13.7 million as of December 31, 2019. The reduction in cash balance over the fiscal year is the result of cash used for operating activities including regulatory expenses associated with the regulatory submissions of PEDMARK and expenses associated with commercial launch preparation.
- **Research and Development (R&D) Expenses** – R&D expenses were $1.2 million and $5.6 million, respectively, for the fourth quarter and year ended December 31, 2019, compared to $1.7 million and $5.0 million for the same period in 2018. The Company completed a significant part of the activities needed for regulatory approval of PEDMARK during the fourth quarter of 2019.
- **General and Administrative (G&A) Expenses –** G&A expenses were $2.5 million and $7.4 million, respectively, for the fourth quarter and year ended December 31, 2019, compared to $1.4 million and $5.4 million, respectively for the same periods in 2018. Fourth quarter increase in G&A was largely attributable to the commercialization efforts as the Company prepares to bring PEDMARK, if approved, to market in the second half of 2020. An additional increase in G&A expenses is attributed to a small rise in compensation to officers, directors and key contract employees in fiscal 2019 as compared to fiscal 2018. Shareholders passed a motion to increase the duration of all outstanding option contracts to a total of 10 years in 2019. This added $1.3 million in G&A in non-cash compensation over the prior year. Sales and marketing expenses increased by $0.4 million over the prior year as the Company began to focus efforts to commercialize PEDMARK. The company incurred approximately $0.25 million in additional administrative expenses as it added positions to the commercial team including the addition of a Chief Commercial Officer.
- **Net Loss** - Net losses for the fourth quarter and year ended December 31, 2019 of $3.6 million ($0.18 per share) and $12.8 million ($0.64 per share), respectively, compared to $3.0 million ($0.15 per share) and $9.9 million ($0.52 per share), respectively, for the same periods in 2018.
- **Financial Guidance** - The Company believes its cash and cash equivalents on hand as of December 31, 2019, along with the $12.5 million loan facility available upon FDA approval of PEDMARK™ will be sufficient to fund the Company's planned commercial launch of PEDMARK™ in the second half of 2020.

Financial Update

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements which were prepared in accordance with U.S. generally accepted accounting principles. The complete audited condensed consolidated financial statements for the period ended December 31, 2019 and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

Audited Condensed Consolidated
Statement of Operations:
(U.S. Dollars in thousands except per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	1,172	1,723	5,607	5,008
General and administrative	2,481	1,382	7,402	5,401
Loss from operations	(3,653)	(3,105)	(13,009)	(10,409)
Other (expense)/income				
Unrealized gain/(loss) on derivatives	-	-	-	167
Amortization expense	(18)	-	(64)	-
Other loss	(8)	6	(17)	6
Net interest income	69	115	315	348
Total other (expense)/income, net	43	121	234	521
Net income/(loss)	$ (3,610)	$ (2,984)	$ (12,775)	$ (9,888)
Basic net income/(loss) per common share	$ (0.18)	$ (0.15)	$ (0.64)	$ (0.52)
Diluted net income/(loss) per common share	$ (0.18)	$ (0.15)	$ (0.64)	$ (0.52)

Fennec Pharmaceuticals Inc.
Balance Sheets
(U.S. Dollars in thousands)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 13,650	$ 22,781
Other current assets	234	169
Non-current assets, net	262	-
Total Assets	$ 14,146	$ 22,950
Liabilities and stockholders' equity		
Current liabilities	$ 2,271	$ 1,637
Total stockholders' equity	11,875	21,313
Total liabilities and stockholders' equity	$ 14,146	$ 22,950

Working Capital	Fiscal Year Ended	
Selected Asset and Liability Data:	December 31, 2019	December 31, 2018
(U.S. Dollars in thousands)		
Cash and cash equivalents	$ 13,650	$ 22,781
Other current assets	234	169
Current liabilities excluding derivative liability	(2,271)	(1,637)
Working capital	$ 11,613	$ 21,313
Selected Equity:		
Common stock & APIC	$ 154,663	$ 151,326
Accumulated deficit	(144,031)	(131,256)
Stockholders' equity	11,875	21,313

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, 2019. Fennec Pharmaceuticals, Inc. 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.

About PEDMARK™ (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 annually that over 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.

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.

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. PEDMARK received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018. 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 (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.

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