

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): May 9, 2019

FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-32295
(Commission File Number)

British Columbia, Canada
(State or other jurisdiction of
incorporation)

20-0442384
(I.R.S. Employer Identification No.)

**PO Box 13628, 68 TW Alexander Drive,
Research Triangle Park, NC**
(Address of principal executive offices)

27709
(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 May 9, 2019, Fennec Pharmaceuticals Inc. issued a news release announcing the first-quarter financial results for the period ended March 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 May 9, 2019](#)

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 May 9, 2019

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



FENNEC PROVIDES BUSINESS UPDATE AND ANNOUNCES FIRST QUARTER 2019 FINANCIAL RESULTS

- Targeting New Drug Application to U.S. FDA for PEDMARK™ in late 2019 to early 2020
- Strong financial position with \$20.2 million in cash and no debt

Research Triangle Park, NC, May 9, 2019 – 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 first quarter ended March 31, 2019.

"We were very pleased with the production transition of PEDMARK™ API to the new commercial drug substance manufacturing site during the first quarter," said Rosty Raykov, chief executive officer of Fennec. "The strength of our cash balance is of utmost importance to us while we remain on track to complete our submission of the NDA for PEDMARK™ in late 2019 to early 2020. We look forward to providing further updates on our progress."

Financial Results for the First Quarter 2019

- **Cash Position** - Cash and cash equivalents were \$20.2 million as of March 31, 2019. The reduction in cash balance over the quarter ended March 31, 2019, is the result of cash used for operating activities including the manufacturing and regulatory expenses associated with the regulatory submissions of PEDMARK™.
- **R&D Expenses** - Research and development (R&D) expenses were \$1.7 million for the three months ended March 31, 2019, compared to \$0.7 million for the same period in 2018. The increase in R&D expenses for the comparative three months, is primarily due to activities associated with the regulatory approvals of PEDMARK™.
- **G&A Expenses** - General and administrative (G&A) expenses were \$1.0 million for the three months ended March 31, 2019, compared to \$1.1 million same period in 2018.
- **Net Loss** - Net loss was \$2.6 million and \$1.6 million for the three months ended March 31, 2019 and 2018, respectively.
- **Financial Guidance** - The Company believes its cash and cash equivalents on hand as of March 31, 2019 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 interim unaudited consolidated financial statements for the period ended March 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.

Interim Unaudited Statement of Operations
(U.S. Dollars in thousands except per share amounts)

	Three Months Ended	
	March 31, 2019	March 31, 2018
Revenue	\$ -	\$ -
Operating expenses		
Research and development	1,671	689
General and administrative	1,009	1,102
Loss from operations	(2,680)	(1,791)
Unrealized gain/(loss)	-	167
Other loss	(12)	(3)
Interest income	66	59
Net loss	<u>\$ (2,626)</u>	<u>\$ (1,568)</u>
Basic and diluted net loss per common share	<u>\$ (0.13)</u>	<u>\$ (0.09)</u>

Fennec Pharmaceuticals Inc.

Balance Sheets

(U.S. Dollars in thousands)

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 20,231	\$ 22,781
Other current assets	112	169
Non-current assets, net	314	-
Total Assets	<u>\$ 20,657</u>	<u>\$ 22,950</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 1,451	\$ 1,637
Derivative liabilities	-	-
Total stockholders' equity	19,206	21,313
Total liabilities and stockholders' equity	<u>\$ 20,657</u>	<u>\$ 22,950</u>

Working Capital

Selected Asset and Liability Data:

(U.S. Dollars in thousands)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 20,231	\$ 22,781
Other current assets	112	169
Current liabilities	(1,451)	(1,637)
Working capital	<u>\$ 18,892</u>	<u>\$ 21,313</u>
Selected Equity:		
Common stock	\$ 106,392	\$ 106,392
Accumulated deficit	(133,882)	(131,256)
Stockholders' equity	19,206	21,313

At March 31, 2019, the Company had working capital balance totaling approximately \$18.9 million compared to \$21.3 million as of December 31, 2018.

Dollar and shares in thousands	Three Months Ended March 31,	
Selected cash flow data:	2019	2018
Net cash used in operating activities	\$ (2,479)	\$ (1,727)
Net cash used in investing activities	-	-
Net cash (used in)/provided by financing activities	(71)	186
Decrease in cash and cash equivalents	<u>\$ (2,550)</u>	<u>\$ (1,541)</u>

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, 2018. 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 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 10,000 children may receive platinum-based chemotherapy. 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 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 Sodium Thiosulfate (STS) for the prevention of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK™ received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018. 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.fennecepharma.com.

For further information, please contact:

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