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): November 6, 2023

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 November 6, 2023, Fennec Pharmaceuticals Inc. issued a news release announcing the third quarter financial results for the period ended September 30, 2023. 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 November 6, 2023
104	Cover Page Interactive Data File (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 November 7, 2023

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

Exhibit 99.1

FENNEC PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2023 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ PEDMARK® Net Product Revenue of $6.5 Million, a 96% Increase Compared to Second Quarter ~

~ Strong Commercial Uptake Underscoring Significant Unmet Medical Need ~

~ Received Approval in October 2023 by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. for PEDMARQSI ~

~ Management to Host Conference Call Today at 8:30 a.m. ET ~

Research Triangle Park, NC., Nov. 06, 2023 (GLOBE NEWSWIRE) – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, today reported its financial results for the third quarter ended September 30, 2023 and provided a business update.

"We continued to see strong commercial performance with PEDMARK® in the third quarter demonstrated by net product revenue of $6.5 million representing 96% quarter over quarter growth. PEDMARK® addresses a significant unmet medical need in the pediatric oncology community, and we expect to continue building upon our commercial momentum through expanding the prescriber base and increasing the utilization of the earlier endorsement from the NCCN for PEDMARK® in the adolescent and young adult (AYA) population," said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. "Further, we are pleased with the steady progress that we are making preparing for the launch of PEDMARQSI in Europe, including the recent regulatory approval in the U.K. by the MHRA, as we continue to evaluate the best commercial pathway for the Company in Europe."

Financial Results for the third Quarter 2023

- **Net Sales** – The company recorded net product sales of $6.5 million in the third quarter of 2023 compared to net product sales of $3.3 million in the second quarter of 2023. The Company had gross profit of $6.2 million for the third quarter of 2023. The increase in sales reflects strong growth in new patient starts and account adoption.

- **Cash Position –** Cash and cash equivalents were $12.4 million on September 30, 2023. The decrease in cash and cash equivalents between September 30, 2023, and December 31, 2022, is the result of cash outlays for operating expenses related to the promotion and marketing of PEDMARK® and general and administrative expenses, which were offset by cash inflows primarily from product sales. We anticipate that our cash, cash equivalents and investment securities as of September 30, 2023, when coupled with PEDMARK revenue assumptions will be sufficient to fund our planned operations for at least the next twelve months.

- **Research and Development (R&D) Expenses** – Research and development expenses decreased by $0.8 million for the three months ended September 30, 2023, compared to the same period in 2022. The Company's research and development activities for the quarter ended September 30, 2023 consisted of costs associated with investigator initiated clinical trials. During the same period in 2022 and prior to approval of PEDMARK®, manufacturing costs pertaining to PEDMARK® were allocated to R&D expense in the period incurred, and following approval are reflected in inventory.

- **Selling and Marketing Expenses** – Selling and marketing expenses include remuneration of our sales and marketing employees, dollars spent on marketing campaigns (sponsorships, trade shows, presentations, etc.), and any activities to support marketing and sales activities. Selling and marketing expenses for the third quarter of 2023 were $3.4 million compared to $2.3 million in the second quarter of 2023 as the Company increased marketing in the U.S. and pre-commercialization activities in Europe.

- **General and Administrative (G&A) Expenses –** For the three-month period ended September 30, 2023, G&A expenses decreased by $3.2 million over the same period in 2022. Further, G&A expenses decreased by $1.7 million compared to the second quarter of 2023. The decrease in G&A was primarily because of decreases in non-cash employee remuneration which accounted for $1.0 million of the decrease over same period in 2022. There was a reduction in legal expenses of $0.7 million for the quarter ended September 30, 2023 over the same period in 2022.

- **Net Loss –** Net loss for the quarter ended September 30, 2023, was $1.9 million ($0.07 per share), compared to $8.1 million ($0.31 per share) for the same period in 2022.

Q3 2023 CONFERENCE CALL INFORMATION

The Company will host a conference call today, November 6, at 8:30 a.m. ET, to discuss the Company's financial results from the third quarter, ended September 30, 2023, and provide a business outlook for the remainder of 2023.

To access the conference call, please register at: https://register.vevent.com/register/BId73242c7355a46d19e6aa1ff15435b87. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto www.fennepharma.com and proceed to the News & Events / Event Calendar page under the Investors & Media heading. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to listen to the webcast. A webcast replay of the conference call will also be archived on www.fennecpharma.com for thirty days.

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 unaudited condensed consolidated financial statements for the period ended September 30, 2023, 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.

Unaudited Condensed Consolidated
Statements of Operations:
(U.S. Dollars in thousands except share and per share amounts)

	Three Months Ended	
	September 30, 2023	**September 30, 2022**
Revenue		
PEDMARK product sales, net	$ 6,515	$ —
Cost of products sold	(331)	—
Gross profit	6,184	—
Operating expenses:		
Research and development	12	846
Selling and marketing	3,384	—
General and administrative	3,805	7,053
Total operating expenses	7,201	7,899
Loss from operations	(1,017)	(7,899)
Other (expense)/income		
Unrealized foreign exchange loss	(11)	(4)
Amortization expense	(72)	(64)
Unrealized loss on securities	(13)	(27)
Interest income	102	24
Interest expense	(856)	(119)
Total other (expense)/income	(850)	(190)
Net loss	$ (1,867)	$ (8,089)
Basic net loss per common share	$ (0.07)	$ (0.31)
Diluted net loss per common share	$ (0.07)	$ (0.31)
Weighted-average number of common shares outstanding basic	26,458	26,108
Weighted-average number of common shares outstanding diluted	26,458	26,108

Fennec Pharmaceuticals Inc.

Balance Sheets
(U.S. Dollars and shares in thousands)

	Unaudited September 30, 2023	Audited December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 12,399	$ 23,774
Accounts receivable, net	4,525	1,545
Prepaid expenses	247	770
Inventory	1,755	576
Other current assets	20	63
Total current assets	18,946	26,728
Non-current assets		
Deferred issuance cost, net amortization	82	211
Total non-current assets	82	211
Total assets	$ 19,028	$ 26,939
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,941	$ 2,390
Accrued liabilities	951	2,219
Current portion of lease liability	21	—
Total current liabilities	3,913	4,609
Non-current liabilities		
Term loan	25,000	25,000
PIK interest	937	260
Debt discount	(298)	(361)
Operating lease liability - net of current portion	7	—
Total non-current liabilities	25,646	24,899
Total liabilities	29,559	29,508
Shareholders'(deficit) equity:		
Common stock, no par value; unlimited shares authorized; 26,411 shares issued and outstanding (2022 -26,361)	143,560	142,591
Additional paid-in capital	61,229	56,797
Accumulated deficit	(216,563)	(203,200)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(10,531)	(2,569)
Total liabilities and shareholders' (deficit) equity	$ 19,028	$ 26,939

Working Capital

Working capital	**Fiscal Period Ended**	
Selected Asset and Liability Data:	**September 30, 2023**	**December 31, 2022**
(U.S. Dollars in thousands)		
Cash and equivalents	$ 12,399	$ 23,774
Other current assets	6,547	2,954
Current liabilities	(3,913)	(4,608)
Working capital	$ 15,033	$ 22,120
Selected Equity:		
Common stock and additional paid in capital	204,789	199,388
Accumulated deficit	(216,563)	(203,200)
Shareholders' (deficit) equity	(10,531)	(2,569)

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.[i]

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.[ii] 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.[iii]

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. 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.

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 focused on the development and commercialization of PEDMARK® and Pedmarqsi™ to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission Marketing Authorization in June 2023 for Pedmarqsi. PEDMARK has received Orphan Drug Exclusivity in the U.S. for seven years of market protection and Pedmarqsi has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. 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 reduction of risk 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, 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, 2022. 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.

PEDMARK® and Fennec® are registered trademarks of Fennec Pharmaceuticals Inc.

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

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

[iii] 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.