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): March 21, 2024

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 March 21, 2024, Fennec Pharmaceuticals Inc. issued a news release announcing full year and fourth quarter financial results for the period ended December 31, 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 March 21, 2024
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 March 25, 2024

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

FENNEC PHARMACEUTICALS REPORTS FULL YEAR AND FOURTH QUARTER 2023 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ Achieved PEDMARK® Full-Year 2023 Net Product Sales of $21.3 Million, Including $9.7 Million in Net Product Sales in the Fourth Quarter of 2023 ~

~ Entered Into Exclusive Licensing Agreement to Commercialize PEDMARQSI™ in Europe, Australia and New Zealand for Approximately $43 Million Upfront and Up to Approximately $230 Million in Additional Commercial and Regulatory Milestones, and Tiered Royalties Up to the Mid-Twenties ~

~ Pro forma fourth quarter cash in excess of $55 million ~

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

Research Triangle Park, NC, March 21, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the fiscal year ended December 31, 2023 and provided a business update.

"It was an exciting year for Fennec given the strong performance with PEDMARK® in the first full fiscal year following its U.S. commercial launch. We are pleased with our execution against strategic plans and our momentum in 2023, which sets the stage for further success in 2024 and beyond. We also received European Commission and U.K. approvals of PEDMARQSI™, which led to the recent announcement of an exclusive licensing agreement with Norgine for Europe, Australia and New Zealand," said Rosty Raykov, Chief Executive Officer of Fennec Pharmaceuticals. "We have significantly strengthened our balance sheet through the agreement with Norgine, and we remain dedicated to further growing our revenues as we expand the availability of PEDMARK® to patients and providers globally."

Recent Developments and Highlights:

- Entered into exclusive licensing agreement to commercialize PEDMARQSI™ in Europe, Australia and New Zealand. Fennec received approximately $43 million upfront and has the potential to receive up to approximately $230 million in additional commercial and regulatory milestones, and double-digit tiered royalties up to the mid-twenties. PEDMARQSI was granted EU marketing authorization by the European Commission in June 2023, and received UK approval from the MHRA in October 2023.

- Achieved PEDMARK net product revenue of approximately $9 million and $21 million for the fourth quarter and full year 2023, respectively. Additionally, anticipate continued increasing utilization of the earlier endorsement from the NCCN for PEDMARK® in the adolescent and young adult (AYA) population.

- In January 2024, the FDA issued a public reminder to healthcare providers that PEDMARK (sodium thiosulfate injection) is not substitutable with other sodium thiosulfate products as explicitly directed in its prescribing label.

Financial Results for the Fourth Quarter and Fiscal Year Ended December 31, 2023

- **Net Sales –** Net product sales of $21.3 million in fiscal 2023 compared to $1.5 million in 2022. The Company had gross profit of $20.0 million for fiscal year ended 2023. The increase in sales reflects strong growth in new patient starts and accounts.

- **Cash Position –** Cash and cash equivalents were $13.2 million as of December 31, 2023. There was a $10.5 million decrease in cash and cash equivalents between December 31, 2023 and December 31, 2022 as a result of cash outlays for operating expenses related to the promotion and marketing of PEDMARK®, general and administrative expenses and the preparation for the commercial launch of PEDMARQSI in Europe. These cash outflows were offset by cash inflows primarily from product sales. In addition, as announced this week, we received approximately $43 million from the licensing of Europe, Australia and New Zealand to Norgine. Inclusive of these events, the pro forma December 31, 2023 cash balance is in excess of $55 million. We anticipate that our cash, cash equivalents and investment securities as of December 31, 2023, when coupled with PEDMARK revenue assumptions and the recently announced license agreement for Europe, will be sufficient to fund our planned operations for at least the next twelve months.

- **Research and Development Expenses (R&D) Expenses** – R&D expenses decreased by $3.5 million in fiscal 2023 as compared to fiscal 2022. The Company reduced research and development costs when it received FDA approval of PEDMARK® in September 2022. The majority of traditional research and development expenses associated with PEDMARK® are now recorded as general and administrative expenses or capitalized into inventory and eventually recorded to costs of product sales.

- **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. The Company recorded $12.1 million in selling and marketing expenses in fiscal 2023, compared to $2.8 million in fiscal year 2022.

- **General and Administrative (G&A) Expenses** – For fiscal 2023, G&A expenses increased by $2.3 million compared to fiscal 2022. Non-cash expenses associated with equity remuneration increased by $1.4 million in fiscal year 2023 over 2022. Payroll and benefits related expenses rose by $1.1 million in fiscal 2023 compared to fiscal 2022. There was an increase in consulting and professional costs of $0.8 million in fiscal 2023 over fiscal 2022.

- **Net Loss –** Net losses for the fourth quarter and year ended December 31, 2023, of $2.7 million ($0.10 per share) and $16.0 million ($0.60 per share), respectively, compared to $6.9 million ($0.26 per share) and $23.7 million ($0.90 per share), respectively, for the same periods in 2022.

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, 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.

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

	Three Months Ended		Twelve Months Ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Revenue				
PEDMARK product sales, net	$ 9,735	$ 1,535	$ 21,252	$ 1,535
Cost of products sold	(685)	(86)	(1,259)	(86)
Gross profit	9,050	1,449	19,993	1,449
Operating expenses:				
Research and development	32	117	56	3,531
Selling and marketing	3,868	2,785	12,123	2,785
General and administrative	6,968	4,682	20,585	17,722
Total operating expenses	10,868	7,584	32,764	24,038
Loss from operations	(1,818)	(6,135)	(12,771)	(22,589)
Other (expense)/income				
Unrealized foreign exchange gain (loss)	2	(58)	5	(9)
Amortization expense	(70)	(70)	(287)	(149)
Unrealized gain (loss) on securities	4	(3)	(39)	(184)
Interest income	115	153	441	195
Interest expense	(915)	(744)	(3,394)	(978)
Total other (expense)/income	(864)	(722)	(3,274)	(1,125)
Net loss	$ (2,682)	$ (6,857)	$ (16,045)	$ (23,714)
Basic net loss per common share	$ (0.10)	$ (0.26)	$ (0.60)	$ (0.90)
Diluted net loss per common share	$ (0.10)	$ (0.26)	$ (0.60)	$ (0.90)
Weighted-average number of common shares outstanding, basic	26,833	26,275	26,574	26,275
Weighted-average number of common shares outstanding, diluted	26,833	26,275	26,574	26,275

Audited Consolidated Balance Sheets:
(U.S. Dollars in thousands)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 13,269	$ 23,774
Accounts receivable, net	8,814	1,545
Prepaid expenses	583	770
Inventory	2,156	576
Other current assets	21	63
Total current assets	24,843	26,728
Non-current assets		
Deferred issuance cost, net amortization	2,021	211
Total non-current assets	2,021	211
Total assets	$ 26,864	$ 26,939
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 3,799	$ 2,390
Accrued liabilities	3,754	2,219
Total current liabilities	7,553	4,609
Long term liabilities		
Term loan	30,000	25,000
PIK interest	1,219	260
Debt discount	(286)	(361)
Total long term liabilities	30,933	24,899
Total liabilities	38,486	29,508
Commitments and Contingencies		
Shareholders'(deficit) equity:		
Common stock, no par value; unlimited shares authorized; 26,361 shares issued and outstanding (2022 -26,014)	144,307	142,591
Additional paid-in capital	60,073	56,797
Accumulated deficit	(219,245)	(203,200)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(11,622)	(2,569)
Total liabilities and shareholders' (deficit) equity	$ 26,864	$ 26,939

Working capital Selected Asset and Liability Data:	Fiscal Year Ended December 31, 2023	 December 31, 2022
(U.S. Dollars in thousands)		
Cash and equivalents	$ 13,269	$ 23,774
Other current assets	11,574	2,954
Current liabilities	(7,553)	(4,608)
Working capital	$ 17,290	$ 22,120
Selected Equity:		
Common stock and additional paid in capital	206,380	199,388
Accumulated deficit	(219,245)	(203,200)
Shareholders' equity	(11,622)	(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.[7] 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® to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and has received Orphan Drug Exclusivity in the U.S. 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, 2023. 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:

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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.