

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 10, 2025

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))

Securities registered pursuant to Section 12 of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common shares, no par value	FENC	Nasdaq Capital Market

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 2.02. Results of Operations and Financial Condition.

On March 10, 2025, Fennec Pharmaceuticals Inc. issued a news release announcing full year and fourth quarter financial results for the period ended December 31, 2024. 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 10, 2025](#)

Exhibit 104 Cover Page Interactive Data File (the cover page XBRL tags are 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 10, 2025

By: /s/ Robert Andrade

Robert Andrade
Chief Financial Officer



FENNEC PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL-YEAR 2024 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ Achieved Full-Year PEDMARK® Net Product Sales of \$29.6 Million, Up 40% Year-Over-Year, and Generated PEDMARK® Q4 2024 Net Product Sales of \$7.9 Million ~

~ Delivered Q4 2024 EBITDA Loss of \$0.6 Million and Company Has \$26.6 Million in Cash, Cash Equivalents and Short-Term Investments ~

~ Completed Early Repayment of \$13 Million of the Company's Convertible Debt Facility ~

~ Continued Momentum in the Adolescent and Young Adult (AYA) Segment and Academic Setting Following Strategic Investments to Drive Awareness of Ototoxicity & Adoption of PEDMARK® ~

~ PEDMARQSI® Now Commercially Available to Patients and Healthcare Providers in the United Kingdom and Germany ~

~ Japan Clinical Trial (STS-J01) Results Expected in the Second Half of 2025 ~

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

Research Triangle Park, NC, March 10, 2025 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the fiscal year ended December 31, 2024 and provided a business update.

"2024 marked the beginning of a foundational transformation for Fennec, setting the stage for the PEDMARK® strategy that we are utilizing throughout 2025 to realize our next phase of growth. With key management and commercial hires in Q3 and Q4, we strengthened our leadership team and with this enhanced expertise, we are now well-positioned to drive execution and excellence in the field. We are seeing encouraging momentum in early 2025, particularly with adoption by academic institutions and new patient segments, reinforcing the value and need for PEDMARK®," said Jeff Hackman, chief executive officer of Fennec Pharmaceuticals. "Global access to PEDMARK® has also expanded meaningfully, with recent PEDMARQSI® commercial launches in the United Kingdom and Germany in 2025. With the right foundational strategies now in place, we are confident that our strong and focused execution will translate into significant shareholder value in 2025 and beyond."

Business Highlights:

- **U.S. Clinical Compendia Update:** All medical compendia have incorporated Fennec's clinical updates, and AHFS, the largest online platform for pharmacists, has updated its content to reflect and differentiate PEDMARK® in accordance with its labeling. We also continue to advance our efforts to have PEDMARK® added to the NCCN Drug and Biologics Compendium®, a key step in further expanding access and reimbursement pathways.
 - **PEDMARQSI® Commercial Launch in Europe:** In December 2024, Norgine received positive guidance from National Institute for Health and Care Excellence (NICE) recommending PEDMARQSI® for the prevention of cisplatin-induced hearing loss in patients (aged 1 month to 17 years) with localized, non-metastatic,
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solid tumors and PEDMARQSI® is currently available in the U.K. In February 2025, Norgine announced that it has commercially launched PEDMARQSI® in Germany. Both milestones mark an important step in achieving Fennec's mission of expanding access to PEDMARQSI® to cancer patients across the globe at risk of hearing loss.

- **Ex-U.S. Opportunities for PEDMARK®:** In Japan, the investigator-initiated clinical trial (STS-J01) in Japan evaluating PEDMARK® fully enrolled in Q4 2024 and the results of the trial are expected in the second half of 2025 with the potential evaluation for registration of PEDMARK® in Japan thereafter. Further, Fennec has partnered with Inpharmus, formerly named TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC, for the distribution of PEDMARK® in Turkey and Gulf Cooperation Council Countries.
- **Early Repayment of \$13 Million of the Company's Approximately \$32 Million Outstanding Convertible Debt Facility:** In December 2024, Fennec announced the early partial repayment of a significant portion of its debt to Petrichor in a financial and strategic action that optimizes the Company's balance sheet and overall capital structure, while effectively saving approximately \$1.5 million in future annual interest payments and eliminating potential dilutive shares.

Financial Results for the Fourth Quarter and Full Fiscal Year Ended December 31, 2024

- **Net Product Sales** – For the fourth quarter of 2024, the Company recorded net product sales of \$7.9 million compared to \$7.0 million in the third quarter of 2024, representing an increase of approximately 13%. For the full fiscal year (FY) 2024, the Company recorded \$29.6 million compared to \$21.3 million in 2023, representing an increase of approximately 40%. The increase in sales in both the quarter and year reflects strong growth in accounts and increased penetration in the AYA market opportunity.
- **Cash Position** – Cash and cash equivalents were \$26.6 million as of December 31, 2024. Of note, for the fourth quarter of 2024, our cash flow from operations decreased by \$0.6 million. For the FY 2024, there was a \$13.4 million increase in cash and cash equivalents between December 31, 2023 and December 31, 2024. The increase in cash was primarily due to the \$43 million in upfront cash from the Norgine transaction and cash collected from product sales offset by operating expenses and the \$13 million convertible debt paydown in December 2024.
- **Selling and Marketing Expenses** – The Company recorded \$3.9 million in selling and marketing expenses in the fourth quarter of 2024 compared to \$4.6 million in the third quarter of 2024. For the FY 2024, the Company recorded \$18.4 million in selling and marketing compared to \$12.1 million in fiscal year 2023. The increase is largely related to increased payroll and additional marketing expenses in the comparable periods as we focused on expanding our outreach to community oncology centers and the adolescent and young adult (AYA) population.
- **General and Administrative (G&A) Expenses** – The Company recorded \$4.1 million in G&A expenses fourth quarter of 2024 compared to \$7.0 million in the third quarter of 2024. For the FY 2024, the Company recorded \$23.1 million in G&A expenses compared to \$20.6 million in fiscal year 2023. For the fourth quarter of 2024, G&A expenses decreased due largely to lower cash based stock compensation and a one-time severance payment related to the previous CEO in the third quarter. For the full year G&A expenses were higher both due to European pre-commercialization related expenses, expenses associated with the Norgine transaction and intellectual property expenses related to ongoing litigation.

Fourth Quarter and Full-Year 2024 Conference Call Information

Date: Monday, March 10, 2025

Time: 8:30 a.m. ET

Webcast Link: <https://edge.media-server.com/mmc/p/7bafbd7q>

Participant Link: <https://register.vevent.com/register/Bleb244773eed644bd83882935e4272e91>

To access the live webcast link, log onto www.fennecpharma.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 audited condensed consolidated financial statements for the period ended December 31, 2024 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 Consolidated
Statements of Operations:
(U.S. Dollars in thousands except per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
Revenue				
Product sales, net	\$ 7,925	\$ 9,735	\$ 29,580	\$ 21,252
Licensing revenue	—	—	17,958	—
Total revenue	<u>7,925</u>	<u>9,735</u>	<u>47,538</u>	<u>21,252</u>
Operating expenses:				
Cost of product sales	669	685	3,184	1,259
Research and development	50	32	307	56
Selling and marketing	3,944	3,868	18,426	12,123
General and administrative	4,196	6,968	23,053	20,585
Total operating expenses	<u>8,859</u>	<u>11,553</u>	<u>44,970</u>	<u>34,023</u>
Loss from operations	<u>(934)</u>	<u>(1,818)</u>	<u>2,568</u>	<u>(12,771)</u>
Other (expense)/income				
Realized foreign exchange (loss)/gain	(27)	2	(82)	5
Amortization expense	(25)	(70)	(89)	(287)
Unrealized loss on securities	(66)	4	(80)	(39)
Interest income	399	115	1,682	441
Interest expense	(966)	(915)	(4,069)	(3,394)
Total other (expense)/income	<u>(685)</u>	<u>(864)</u>	<u>(2,638)</u>	<u>(3,274)</u>
Net (loss) / income	<u>\$ (1,619)</u>	<u>\$ (2,682)</u>	<u>\$ (70)</u>	<u>\$ (16,045)</u>
Basic net loss per common share	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.00)</u>	<u>\$ (0.60)</u>
Diluted net loss per common share	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.00)</u>	<u>\$ (0.60)</u>
Weighted-average number of common shares outstanding basic	<u>27,460</u>	<u>26,833</u>	<u>27,294</u>	<u>26,574</u>
Weighted-average number of common shares outstanding diluted	<u>27,460</u>	<u>26,833</u>	<u>27,294</u>	<u>26,574</u>

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

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 26,634	\$ 13,269
Accounts receivable, net	12,884	8,814
Prepaid expenses	3,080	583
Inventory	1,060	2,156
Other current assets	364	21
Total current assets	44,022	24,843
Non-current assets		
Other non-current assets, net of amortization	924	2,021
Total non-current assets	924	2,021
Total assets	\$ 44,946	\$ 26,864
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 2,875	\$ 3,778
Accrued liabilities	3,428	3,754
Operating lease liability - current	248	21
Contract liability - current	2	—
Total current liabilities	6,553	7,553
Long term liabilities		
Term loan	18,206	30,000
PIK interest	1,271	1,219
Debt discount	(139)	(288)
Contract liability - long-term	24,561	2
Total long term liabilities	43,899	30,933
Total liabilities	50,452	38,486
Commitments and Contingencies		
Shareholders' (deficit) equity:		
Common stock, no par value; unlimited shares authorized; 27,292 shares issued and outstanding (2023 -26,361)	145,608	144,307
Additional paid-in capital	66,958	62,073
Accumulated deficit	(219,315)	(219,245)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(5,506)	(11,622)
Total liabilities and shareholders' (deficit) equity	\$ 44,946	\$ 26,864

Working capital Selected Asset and Liability Data: (U.S. Dollars in thousands)	Fiscal Year Ended	
	December 31, 2024	December 31, 2023
Cash and equivalents	\$ 26,634	\$ 13,269
Other current assets	17,388	11,574
Current liabilities	6,553	7,553
Working capital	\$ 37,469	\$ 17,290

Selected Equity:

Common stock and additional paid in capital	212,566	206,380
Accumulated deficit	(219,315)	(219,245)
Shareholders' equity	(5,506)	(11,622)

About Cisplatin-Induced Ototoxicity

Cisplatin and other platinum compounds are essential chemotherapeutic agents for the treatment of many 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 first and only therapeutic agent with proven efficacy and safety data with an established dosing regimen, across two open-label, randomized Phase 3 clinical studies, the Children's Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

As a reminder, PEDMARK 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. PEDMARK is recommended for the AYA population by the National Comprehensive Cancer Network, or NCCN, with a 2A endorsement.

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/1.73m².

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 European Commission approval in June 2023 and U.K. approval in October 2023 under the brand name PEDMARQSI[®]. PEDMARK has received Orphan Drug Exclusivity in the U.S. and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. 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®/PEDMARQSI[®], the market opportunity for and market impact of PEDMARK®/ PEDMARQSI[®], its potential impact on patients and anticipated benefits associated with its use, future commercial and regulatory milestone and royalty payments from Norgine, 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, 2024. 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® PEDMARQSI® 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.
