

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 8-K/A
(Amendment No. 1)**

**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 29, 2024

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(b) 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.

Background.

This Amendment No. 1 to the Current Report on Form 8-K/A hereby amends and restates the Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 29, 2024 to properly disclose the results of operations and financial condition of Fenec Pharmaceuticals Inc. (“Fenec” or the “Company”) under Item 2.02.

Item 2.02 Results of Operations and Financial Condition.

On February 29, 2024, Fenec issued a press release announcing financial results for the fourth quarter and full-year ended December 31, 2023. A copy of the Press Release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference in this Item 2.02. The press release did not include certain financial statements, related footnotes and certain other financial information that will be filed with the Securities and Exchange Commission as part of the Company’s Annual Report on Form 10-K.

The information and exhibit contained in this Item 2.02 is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

[99.1](#) [Press Release dated February 29, 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.

Date: March 6, 2024

FENNEC PHARMACEUTICALS INC.

By: /s/ Rostislav Raykov
Rostislav Raykov
Chief Executive Officer



Fennec Pharmaceuticals Reports Preliminary Unaudited Net Revenue for Fourth Quarter and Full-Year 2023 Results

~ Fourth Quarter 2023 Net Revenues of Approximately \$9.2 to \$9.7 Million ~

~ Company Expects to Report 2023 Fourth Quarter and Audited Full-Year Results on or about March 26, 2024 ~

RESEARCH TRIANGLE PARK, N.C., February 29, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, today announced preliminary unaudited fourth quarter and full-year 2023 net revenues.

The information in this press release is based upon preliminary unaudited information and management estimates for the fourth quarter 2023 and is subject to the completion of Fennec's financial closing procedures and year end audit.

Preliminary Unaudited 2023 Fourth Quarter Revenue and Year End Performance:

- Fourth quarter 2023 net revenues are expected to be approximately \$9.2 to \$9.7 million, which represents approximately a 41-49% increase over the third quarter of 2023.
- Full-year 2023 net revenues are expected to be approximately \$20.7 to \$21.2 million.

Fennec expects to report its 2023 fourth quarter and audited full-year year results of operations on or about March 26, 2024.

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.

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.

For further information, please contact:

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