UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K/A

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 3, 2023

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. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 3, 2023, Fennec Pharmaceuticals Inc. issued a press release announcing that Adrian Haigh had stepped down from the the position of Director of Fennec Pharmaceuticals Inc. In the same press release it was announced that Mr. Haigh had accepted the appointment as Chief Operating Officer. A copy of the news release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

There were no arrangements or understandings between Mr. Haigh and any other person pursuant to which Mr. Haigh was appointed as a management team member, and there are no related party transactions between Mr. Haigh and the Company.

Mr. Haigh, age 63, is a proven leader with decades of global commercial experience successfully building and executing the launch of several oncology products. Mr. Haigh retired from PTC Therapeutics on Dec 31st 2022, his last role at PTC was Senior Vice President and Head of International, he joined the company in 2014 as Head of EMEA and built the company's international organization. Previously Mr. Haigh served as Chief Operating Officer at Gentium GmbH since March 2011. Prior to joining Gentium, Mr. Haigh served as Regional VP Commercial Operations at Biogen Idec where he managed several affiliates and also the global distributor business and prior to that was the General Manager of Amgen Nordic and Portugal. He served as the Executive Vice President of Global Marketing and Corporate Planning at EUSA Pharma and joined EUSA from Amgen where he led the international oncology franchise. Mr. Haigh previously has held senior commercial and marketing positions at SmithKline Beecham, Schering Plough, Organon and Novo Nordisk.

It is anticipated that Mr. Haigh will commence employment on August 3, 2023. Mr. Haigh's initial base salary will be at the rate of €400,000 per year. He shall be entitled to receive an annual discretionary bonus with a target (the "Target Bonus") of forty percent (40%) of Mr. Haigh's base salary per 12-month period (which may be pro-rated for any partial period of less than 12 months), based upon a determination by the CEO and, where applicable, the Company's Board of Directors (the "Board") of the achievement of objectives to be set from time to time by the Board, provided that Mr. Haigh must remain employed through the payment date in order to earn the bonus. In addition, Fennec will grant Mr. Haigh 200,000 options to purchase common shares which (i) have an exercise price per share equal to the "Fair Market Value" (as defined in Company's Option Plan); (ii) have a term of ten years and one-third of which shall vest one year after the date of the grant and the balance thereof shall vest monthly thereafter for two years in equal increments, and (iii) be otherwise on the terms and conditions set forth in the Company's Option Plan.

If Mr. Haigh's employment is terminated by the Company (other than for cause) or by the Mr. Haigh for "good reason", and such termination, then, following such termination, Mr. Haigh shall be entitled to continue to receive the following as severance (the "Severance Benefits"):

(i) an amount equal to:

(x) three (3) months of Mr. Haigh's Base Salary, or

(y) if such termination occurs either (a) after the second anniversary of the Effective Date or (b) as a result of a Change of Control as defined in 8F, six (6) months of Mr. Haigh's Base Salary,

in either case, minus any federal, state and local payroll taxes and other withholdings legally required or properly requested by Mr. Haigh. The applicable foregoing amount shall be paid to Mr. Haigh in full within five (5) days of termination.

(ii) a *pro rata* share of any Target Bonus earned by Mr. Haigh for the year in which the termination takes place, minus any federal, state and local payroll taxes and other withholdings legally required or properly requested by Mr. Haigh; and

(iii) acceleration of vesting of stock options as a result of such termination;

provided, however, Mr. Haigh shall receive no Severance Benefits unless Mr. Haigh executes and delivers to the Company, in a form acceptable to the Company and its counsel, a general release of claims against the Company (a "Release"), which Release is not revoked within any time period allowed for revocation under applicable law.

The foregoing description of Mr. Haigh's employment agreement is not complete and is subject in all respects to the complete terms of such agreement, a copy of which is attached as Exhibit 10.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
Exhibit 99.1	Press Release dated August 3, 2023
Exhibit 10.1	Employment Agreement Adrian Haigh
Exhibit 104	Cover Page Interactive Data File (embedded as 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 August 4, 2023

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

Exhibit 10.1

August 3, 2023

Dear Adrian

On behalf of the Board of Directors of Fennec Pharmaceuticals Inc. ("Fennec" or the "Company"), I am pleased to make you an executable offer to join Fennec Pharmaceuticals EU Limited, a wholly owned subsidiary of Fennec, as its Chief Operating Officer ("COO"). The purpose of this agreement is to clarify the terms of Employee's "at will" employment with the Company, including Employee's compensation level and benefit entitlements.

1. **Employment and Duties.**

A. The Company hereby agrees to employ Employee as COO of the Company and its parent corporation, Fennec Pharmaceuticals Inc. (the "Parent"), effective as of August 3, 2023 (the "Effective Date"). In that position, Employee will report directly to the Company's Chief Executive Officer, and Employee hereby agrees to accept such employment upon the terms and conditions hereinafter set forth.

B. Employee will perform the duties inherent in Employee's position in good faith and in a reasonable and appropriate manner. Employee will be expected to travel per their territory alignment as reasonably necessary or advisable to perform and fulfill Employee's responsibilities under this Agreement. While employed by the Company, you agree to work on a full-time basis exclusively for the Company and agree that you shall not, while you are employed by the Company, be employed or engaged in any capacity, in promoting, undertaking or carrying on any other business that competes with the Company or interferes or could reasonably interfere with your duties to the Company without our prior written permission. It is noted that you currently hold non-executive director positions with PTC Therapeutics International and Medison Pharma and the Company grants permission for these to continue.

C. Employee shall be employed by the Company on an "at will" basis, meaning either the Company or Executive may terminate Employee's employment at any time, with or without cause or advance notice except as specifically set forth in Section 8 of this Agreement. Any contrary representations that may have been made to Employee shall be superseded by this Agreement. This Agreement (inclusive of the Proprietary Information and Inventions Agreement incorporated herein) shall constitute the full and complete agreement between Employee and the Company on the "at will" nature of Employee's employment with the Company, which may be changed only in an express written agreement signed by Employee and a duly authorized officer of the Company.

2. **Compensation.**

A. Employee's initial base salary will be at the rate of EUR400,000 per year. Employee's base salary will be subject to adjustment by the Company's Board of Directors on an annual basis.

B. Employee shall be entitled to receive an annual discretionary bonus with a target (the "Target Bonus") of forty percent (40%) of Employee's base salary per 12-month period (pro-rated for any partial period of less than 12 months), based upon a determination by the CEO and, where applicable, the Company's Board of Directors (the "Board") of the achievement of objectives to be set from time to time by the Board, provided that Employee must remain employed through the payment date in order to earn the bonus. The measurement period for this purpose will end on approximately December 31 of each year. The annual discretionary bonus, if otherwise earned subject to continued employment through the payment date, will be paid as soon as practicable after the achievement of objectives for the measurement period has been determined, but in no event will such bonus be paid after March 31 for the preceding measurement period. The Company may modify Employee's compensation and benefits from time to time at its sole discretion.

C. Employee shall be entitled to receive reimbursement for international tax services required as employee of Fennec up to an amount not to exceed EUR20,000.

D. Employee's base salary will be paid in 12 monthly installments . The Company will deduct and withhold, from the base salary and bonuses payable to Employee hereunder, any and all applicable income and employment withholding taxes and any other amounts required to be deducted or withheld by the Company under applicable statute or regulation.

3. **Employee Stock Options.**

A. Upon commencement of employment, subject to Board approval and any black-out restrictions, Fennec will grant Employee 200,000 options to purchase common shares (the "Equity Options"). The Equity Options shall: (i) have an exercise price per share equal to the "Fair Market Value" (as defined in Plan); (ii) have a term of ten years, subject to early termination in accordance with the Plan; (iii) vest, as to one-third of the Equity Options, on the first anniversary of the date of the grant, and vest, as to the balance of the Equity Options, in equal monthly instalments after such first anniversary for two years, and (iv) be otherwise on the terms and conditions set forth in the Plan;

B. At the discretion of the Company's Board of Directors, Employee may be granted stock option awards in addition to the Equity Options described in 3(A).

4. **Expense Reimbursement.** Employee will be entitled to reimbursement from the Company for all customary, ordinary and necessary business expenses incurred by Employee in the performance of Employee's duties hereunder in accordance with the Company policies, provided Employee furnish the Company with vouchers, receipts and other details of such expenses within ninety (90) days after they are incurred. Monthly cell phone reimbursement of EUR200 and Wi-Fi of EUR200 will begin at hire date.

5. **Fringe Benefits.** Employee will be eligible to participate in any group life insurance plan, group medical and/or dental insurance plan, accidental death and dismemberment plan, short-term disability program and other employee benefit plans, including any company pension plan or employee stock purchase plan if and when established, which are made available to employees of the Company and for which Employee otherwise qualifies.

6. **Vacation.** Employee will accrue five(5) weeks of paid vacation benefits per year in accordance with the Company policy in effect for employees, as well as company holidays, as laid out in the company benefits plan

7. **Proprietary Information.** Prior to commencement of Employee's services as COO, Employee will sign and deliver to the Company the standard-form Proprietary Information and Inventions Agreement required of all key employees of the Company.

8. **Termination of Employment.**

A. Employee's employment shall commence as of the Effective Date and shall continue for a period of one (1) year unless terminated by either party at least thirty (30) days prior to the expiry of such one year period, *provided, however* that the term of this Agreement shall be extended automatically for additional one-year periods (each, a "Renewal Term").

B. The Company may terminate Employee's employment under this agreement at any time for any reason by providing Employee with at least fifteen (30) days prior written notice. However, such notice requirement is not required if Employee's employment is terminated for cause as described in subparagraph 8(D) below.

C. If Employee's employment is terminated by the Company (other than for cause) pursuant to Subsection 8(B) or by the Employee for "good reason" pursuant to Subsection 8(F), and such termination is not for any of the reasons set out in Subsections 8(D), then, following such termination, Employee shall be entitled to continue to receive the following as severance (the "Severance Benefits"):

(i) an amount equal to:

(x) three (3) months of Employee's Base Salary, or

(y) if such termination occurs either (a) after the second anniversary of the Effective Date or (b) as a result of a Change of Control as defined in 8F, six (6) months of Employee's Base Salary,

in either case, minus any federal, state and local payroll taxes and other withholdings legally required or properly requested by Employee. The applicable foregoing amount shall be paid to Employee in full within five (5) days of termination.

(ii) a *pro rata* share of any Target Bonus earned by Employee for the year in which the termination takes place, minus any federal, state and local payroll taxes and other withholdings legally required or properly requested by Employee

(iii) In addition, in case of a change of control, all your unvested stock options will become fully vested and exercisable of the date of termination or resignation of employment and shall be

D. The Company may at any time, upon written notice, terminate Employee's employment hereunder for cause as described in (i) and (ii) below. Such termination will be effective immediately upon such notice and, for the avoidance of doubt, Employee will not be entitled to any advance notice or Severance Benefits, as a result of such termination.

For purposes of this agreement, Employee's employment with the Company will be deemed to have been involuntarily terminated for cause if Employee's services are terminated by the Company for one or more of the following reasons:

(i) acts of fraud or embezzlement or other intentional misconduct which materially adversely affects the Company's business, or

(ii) misappropriation or unauthorized disclosure or use of the Company's proprietary information.

E. Employee's employment shall automatically terminate in the event of Employee's death or permanent disability on the date of his death or permanent disability, as applicable. However, all the Severance Benefits described in Section 8(C) shall be extended to Employee or Employee's beneficiaries, as applicable, for a period of 12 months. "Permanent disability" in this context means that the Company in good faith has determined, and advised Employee in writing that, the Employee has become incapacitated or disabled in a manner that indefinitely precludes Employee from performing the essential functions of his position with the Company without any reasonable prospect of improvement, and no reasonable accommodations can be made by the Company for Employee to return to work and perform such essential functions.

F. Employee may terminate his employment under this agreement at any time for any reason upon fifteen (15) days prior written notice to the Company. Company may, in its discretion, waive all or any portion of such notice in writing. No Severance Benefits are payable to Employee unless such termination by Employee is for "good reason", as defined below. If the Employee terminates his employment for "good reason", the Employee is entitled to receive the Severance Benefits described in Section 8(C). "Good reason" means: (i) a material decrease in the Employee's title, duties, responsibilities, and/or compensation and benefits, without Employee's prior written consent; (ii) the Company's material breach of its obligations under this employment agreement that has not been cured within seven (7) days after Employee provides written notice of such material breach; (iii) the Parent completes a transaction that constitutes a Change of Control and, in connection therewith or at any time within one (l) year following such Change of Control, any of Employee's title, duties, responsibilities, base salary or reporting structure have materially changed. "Change of Control" shall have the meaning given to such term in the Parent's stock option plan.

9. **Governing Law.** This agreement shall be governed by and construed according to the laws Ireland, without reference to the choice of law or conflict of law provisions of such laws.

10. **Entire Agreement.** This agreement (inclusive of the Proprietary Information and Inventions Agreement incorporated herein) contains the entire agreement and understanding by and between the Company and Employee with respect to the terms described herein, and any representations, promises, agreements or understandings, written or oral, not herein contained shall be of no force or effect. No change or modification hereof shall be valid or binding unless the same is in writing and signed by the parties hereto.

Please indicate your acceptance of the foregoing provisions of this employment agreement by signing the enclosed copy of this agreement and returning it to the Company.

Very truly yours,

Fennec Pharmaceuticals Inc.

By: _____
Name: Rosty Raykov
Title: CEO

ACCEPTED BY AND AGREED TO

_____
Adrian Haigh
Dated: August ____, 2023

Exhibit 99.1

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

~ Growing Physician Awareness and Usage of PEDMARK® Drove Quarterly Revenue Growth of 98% ~

~Fennec Expands Leadership Team with the Appointment of Adrian Haigh as Chief Operating Officer ~

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

Research Triangle Park, NC, August 3, 2023 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, today reported its financial results for the second quarter ended June 30, 2023 and provided a business update.

"During the second quarter, we continued to make strong progress with the U.S. commercial launch of PEDMARK®, delivering net revenue of $3.3 million, which is a 98% increase in net revenue over the first quarter of 2023. These results reflect strong growth in patient starts and new account orders," said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. "Further, we are delighted to announce the appointment of Adrian Haigh, a Fennec board member since 2014, to the position of Chief Operating Officer. Adrian brings significant experience in evaluating business development opportunities and preparing global commercial operations, and we are pleased to have him on our leadership team."

Appointment of Adrian Haigh as Chief Operating Officer

Fennec has expanded its leadership team with the appointment of Adrian Haigh as Chief Operating Officer. Adrian has been a board member of Fennec since 2014 and with his appointment to the management team of Fennec will step down as board member. Adrian recently retired from PTC Therapeutics where his last role was Senior Vice President and Head of International. Previously, Mr. Haigh served as Chief Operating Officer at Gentium GmbH where he built and managed the company's commercial and medical affairs organization and was also responsible for business development, playing a pivotal role in the sale of Gentium to Jazz Pharmaceuticals for $1 billion.

"I am delighted to join Fennec at this critical point in the commercial evolution of the company and to be part of the leadership team that is evaluating all options for PEDMARK® worldwide," said Adrian Haigh. "Further, having been part of Fennec's board for nearly a decade, I will continue Fennec's unrelenting commitment to enabling rapid access to PEDMARK® to all eligible patients as hearing loss from cisplatin chemotherapy is a permanently disabling and devastating side effect of cancer treatment."

Upcoming Investor Conference

- Fennec management will be participating at the 2023 Wedbush PacGrow Healthcare Conference on August 8-9, 2023, at the Lotte Palace Hotel in New York, NY.

Financial Results for the Second Quarter 2023

- **Cash Position** – Cash and cash equivalents were $15.0 million on June 30, 2023. The decrease in cash and cash equivalents between June 30, 2023, and December 31, 2022, is the result of cash outlays for operating expenses related to the promotion and marketing of PEDMARK®, small amounts of research and development and general and administrative expenses, which were offset by cash inflows primarily from product sales of $2.1 million. We anticipate that our cash, cash equivalents and investment securities as of June 30, 2023 will be sufficient to fund our planned operations for at least the next twelve months.

- **Net Sales** – The company recorded net product sales of $3.3 million in the second quarter of 2023 compared to net product sales of $1.7 million in the first quarter of 2023. The Company had gross profit of $3.2 million for the second quarter of 2023. The increase in sales reflects strong growth in new patient starts and account adoption.

- **Research and Development (R&D) Expenses** – Research and development expenses decreased by $1.1 million for the three months ended June 30, 2023, compared to the same period in 2022. The Company's research and development activities for the quarter ended June 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 expensed 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 second quarter of 2023 were $2.3 million compared to $2.5 million in the first quarter of 2023.

- **General and Administrative (G&A) Expenses –** For the three month period ended June 30, 2023, G&A expenses increased by $1.6 million over the same period in 2022. Further, G&A expenses increased by $1.1 million compared to the first quarter of 2023. The increase in G&A was primarily because of increases in non-cash employee remuneration which accounted for $1.5 million of the increase over same period in 2022.

- **Net Loss –** Net loss for the quarter ended June 30, 2023, was $5.4 million ($0.21 per share), compared to $5.1 million ($0.19 per share) for the same period in 2022.

Q2 2023 CONFERENCE CALL INFORMATION

The Company will host a conference call today, August 3, at 8:30 a.m. ET, to discuss the Company's financial results from the second quarter, ended June 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/BIda2814a842e34d0d825731a73c51d74d. 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 June 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 per share amounts)

	Three Months Ended	
	June 30, 2023	**June 30, 2022**
Revenue		
PEDMARK product sales, net	$ 3,325	$ —
Cost of products sold	(148)	—
Gross profit	3,177	—
Operating expenses:		
Research and development	8	1,131
Selling and marketing	2,340	—
General and administrative	5,495	3,878
Total operating expenses	7,843	5,009
Loss from operations	(4,666)	(5,009)
Other (expense)/income		
Unrealized foreign exchange loss	5	1
Amortization expense	(73)	(8)
Unrealized loss on securities	—	(8)
Interest income	115	9
Interest expense	(825)	(57)
Total other (expense)/income	(778)	(63)
Net loss	$ (5,444)	$ (5,072)
Basic net loss per common share	$ (0.21)	$ (0.19)
Diluted net loss per common share	$ (0.21)	$ (0.19)
Weighted-average number of common shares outstanding basic	26,458	26,052
Weighted-average number of common shares outstanding diluted	26,458	26,052

Fennec Pharmaceuticals Inc.
Balance Sheets
(U.S. Dollars in thousands)

	Unaudited June 30, 2023	Audited December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 14,958	$ 23,774
Accounts receivable, net	2,445	1,545
Prepaid expenses	457	770
Inventory	1,439	576
Other current assets	32	63
Total current assets	19,331	26,728
Non-current assets		
Deferred issuance cost, net amortization	106	211
Total non-current assets	106	211
Total assets	$ 19,437	$ 26,939
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 3,005	$ 2,390
Accrued liabilities	773	2,219
Total current liabilities	3,778	4,609
Long term liabilities		
Term loan	25,000	25,000
PIK interest	707	260
Debt discount	(321)	(361)
Total long term liabilities	25,386	24,899
Total liabilities	29,164	29,508
Shareholders'(deficit) equity:		
Common stock, no par value; unlimited shares authorized; 26,411 shares issued and outstanding (2022 -26,361)	143,345	142,591
Additional paid-in capital	60,381	56,797
Accumulated deficit	(214,696)	(203,200)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(9,727)	(2,569)
Total liabilities and shareholders' (deficit) equity	$ 19,437	$ 26,939

Working Capital

Working capital	**Fiscal Period Ended**	
Selected Asset and Liability Data:	**June 30, 2023**	**December 31, 2022**
(U.S. Dollars in thousands)		
Cash and equivalents	$ 14,958	$ 23,774
Other current assets	4,373	2,954
Current liabilities	(3,778)	(4,608)
Working capital	$ 15,553	$ 22,120
Selected Equity:		
Common stock and additional paid in capital	203,726	199,388
Accumulated deficit	(214,696)	(203,200)
Shareholders' (deficit) equity	(9,727)	(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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