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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2023
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from____ to ____

Commission File Number: 001-32295

FENNEC PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

British Columbia, Canada **(State or Other Jurisdiction of Incorporation or Organization)**	**20-0442384** **(I.R.S. Employer Identification No.)**
PO Box 13628, 68 TW Alexander Drive **Research Triangle Park, North Carolina** **(Address of Principal Executive Offices)**	**27709** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (919) 636-4530

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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐
Non-Accelerated Filer ☒
Accelerated Filer ☐
Smaller reporting company ☒
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. ☐

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of November 3, 2023, there were 26,634,676 of the registrant's common shares outstanding.

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PART 1: FINANCIAL INFORMATION
Item 1. Financial Statements
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Condensed Consolidated Balance Sheets
(U.S. Dollars and shares in thousands)
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 12,399	$ 23,774
Accounts receivable, net	4,525	1,545
Prepaid expenses	247	770
Inventory	1,755	576
Other current assets	20	63
Total current assets	18,946	26,728
Non-current assets		
ROU asset non-current	29	—
Deferred issuance costs, net of amortization	53	211
Total non-current assets	82	211
Total assets	$ 19,028	$ 26,939
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,941	$ 2,390
Accrued liabilities	951	2,219
Operating lease liability - current	21	—
Total current liabilities	3,913	4,609
Non-current liabilities		
Term loan	25,000	25,000
PIK interest	937	260
Debt discount	(298)	(361)
Operating lease liability - net of current portion	7	—
Total non-current liabilities	25,646	24,899
Total liabilities	29,559	29,508
Commitments and contingencies (Note 6)		
Stockholders' deficit:		
Common stock, no par value; unlimited shares authorized; 26,635 shares issued and outstanding (2022 - 26,361)	143,560	142,591
Additional paid-in capital	61,229	56,797
Accumulated deficit	(216,563)	(203,200)
Accumulated other comprehensive income	1,243	1,243
Total stockholders' deficit	(10,531)	(2,569)
Total liabilities and holders' deficit	$ 19,028	$ 26,939

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Fennec Pharmaceuticals Inc.
Condensed Consolidated Statements of Operations
(U.S. Dollars and shares in thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue				
PEDMARK® product sales, net	$ 6,515	$ —	$ 11,517	$ —
Cost of products sold	(331)	—	(574)	—
Gross profit	6,184	—	10,943	—
Operating expenses:				
Research and development	12	846	24	3,414
Selling and marketing	3,384	—	8,255	—
General and administrative	3,805	7,053	13,617	13,040
Total operating expenses	7,201	7,899	21,896	16,454
Loss from operations	(1,017)	(7,899)	(10,953)	(16,454)
Other (expense)/income				
Realized foreign exchange (loss)/gain	(11)	(4)	3	(6)
Amortization expense	(72)	(64)	(217)	(79)
Unrealized loss on securities	(13)	(27)	(43)	(126)
Interest income	102	24	326	42
Interest expense	(856)	(119)	(2,479)	(234)
Total other expense	(850)	(190)	(2,410)	(403)
Net loss	$ (1,867)	$ (8,089)	$ (13,363)	$ (16,857)
Basic net loss per common share	$ (0.07)	$ (0.31)	$ (0.50)	$ (0.65)
Diluted net loss per common share	$ (0.07)	$ (0.31)	$ (0.50)	$ (0.65)
Weighted-average number of common shares outstanding basic	26,596	26,108	26,523	26,105
Weighted-average number of common shares outstanding diluted	26,596	26,108	26,523	26,105

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Fennec Pharmaceuticals Inc.
Condensed Consolidated Statements of Stockholders' Equity
Three and Nine Months Ended September 30, 2023, and 2022
(U.S. dollars and shares in thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	**26,361**	**$ 142,591**	**$ 56,797**	**$ (203,200)**	**$ 1,243**	**$ (2,569)**
Stock-based compensation - employees	—	—	1,089	—	—	1,089
Stock option exercise	49	213	—	—	—	213
Restricted stock release	1	—	(20)	—	—	(20)
Net loss	—	—	—	(6,052)	—	(6,052)
Balance at March 31, 2023	**26,411**	**142,804**	**57,866**	**(209,252)**	**1,243**	**(7,339)**
Stock-based compensation - employees	—	—	2,543	—	—	2,543
Stock option exercise	95	541	—	—	—	541
Restricted stock release	3	—	(28)	—	—	(28)
Net loss	—	—	—	(5,444)	—	(5,444)
Balance at June 30, 2023	**26,509**	**143,345**	**60,381**	**(214,696)**	**1,243**	**(9,727)**
Stock-based compensation - employees	—	—	865	—	—	865
Stock option exercise	92	215	—	—	—	215
Restricted stock release	32	—	(17)	—	—	(17)
Net loss	—	—	—	(1,867)	—	(1,867)
Balance at September 30, 2023	**26,633**	**$ 143,560**	**$ 61,229**	**$ (216,563)**	**$ 1,243**	**$ (10,531)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	**26,014**	**$ 140,801**	**$ 53,214**	**$ (179,486)**	**$ 1,243**	**$ 15,772**
Stock-based compensation - employees	—	—	399	—	—	399
Stock-based compensation - consultants	—	—	34	—	—	34
Stock option exercise	26	31	(16)	—	—	15
Restricted stock release	—	—	—	—	—	—
Net loss	—	—	—	(3,696)	—	(3,696)
Balance at March 31, 2022	**26,040**	**140,832**	**53,631**	**(183,182)**	**1,243**	**12,524**
Stock-based compensation - employees	—	—	1,008	—	—	1,008
Stock-based compensation - consultants	—	—	35	—	—	35
Stock option exercise	19	90	(44)	—	—	46
Restricted stock release	8	—	—	—	—	—
Net loss	—	—	—	(5,072)	—	(5,072)
Balance at June 30, 2022	**26,067**	**140,922**	**54,630**	**(188,254)**	**1,243**	**8,541**
Stock-based compensation - employees	—	—	1,853	—	—	1,853
Stock-based compensation - consultants	—	—	34	—	—	34
Warrants issued to creditor	—	—	441	—	—	441
Stock option exercise	151	387	(199)	—	—	188
Restricted stock release	20	—	(166)	—	—	(166)
Net loss	—	—	—	(8,089)	—	(8,089)
Balance at September 30, 2022	**26,238**	**$ 141,309**	**$ 56,593**	**$ (196,343)**	**$ 1,243**	**$ 2,802**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Fennec Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(U.S. Dollars in thousands)
(Unaudited)

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Cash flows (used in) provided by:		
Operating activities:		
Net loss	$ (13,363)	$ (16,857)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt access fees	166	77
Amortization of debt discount	51	2
Unrealized loss on securities	43	126
Stock-based compensation - consultants	—	103
Stock-based compensation - employees	4,497	3,260
Changes in operating assets and liabilities:		
Accounts receivable	(2,980)	—
Prepaid expenses	523	756
Inventory	(1,179)	—
Other assets	—	4
Accounts payable	551	1,756
Accrued liabilities and PIK interest	(592)	(483)
Net cash used in operating activities	(12,283)	(11,256)
Financing activities:		
Long-term debt	—	25,000
Long-term debt paid	—	(5,000)
Issuance of shares, options exercise	969	249
Cash paid for taxes on restricted share release	(61)	(166)
Capitalized deferred issuance costs	—	(175)
Net cash provided by financing activities	908	19,908
Increase/(decrease) in cash and cash equivalents	(11,375)	8,652
Cash and cash equivalents - Beginning of period	23,774	21,100
Cash and cash equivalents - End of period	$ 12,399	$ 29,752
Non-cash investing and financing activities:		
Capitalized lease asset	$ 29	$ —
Warrants issued for long-term debt	$ —	$ 441

The accompanying notes are an integral part of these unaudited condensed consolidated financial statement.

Fennec Pharmaceuticals Inc.
Notes to the Unaudited Interim Condensed Consolidated Financial Statements
(U.S. dollars and shares in thousands, except per share information)

1. Nature of Business and Going Concern

Fennec Pharmaceuticals Inc., a corporation existing under the laws of British Columbia ("Fennec," the "Company," "we," "us," or "our"), was originally formed under the name Adherex Technologies Inc. and subsequently changed its name on September 3, 2014. Fennec is a commercial stage specialty pharmaceutical company with one U.S. Food and Drug Administration ("FDA") approved and European Commission approved product , PEDMARK®, developed to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. The Company has four wholly owned subsidiaries: Oxiquant, Inc. ("Oxiquant") and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc. ("CBI"), a Canadian corporation, and Fennec Pharmaceuticals (EU) Limited ("Fennec Limited"), an Ireland company, collectively referred to herein as the "Company." With the exception of Fennec Pharmaceuticals, Inc. and Fennec Pharmaceuticals (EU) all subsidiaries are inactive.

These unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP") that are applicable to a going concern which contemplates that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of business.

During the three and nine months ended September 30, 2023, the Company incurred a loss from operations of $1,017 and $10,953, respectively. At September 30, 2023, it had an accumulated deficit of $216,563 and had experienced negative cash flows from operating activities during the nine months ended September 30, 2023, in the amount of $12,283.

On August 1, 2022, the Company entered into a Securities Purchase Agreement (the "SPA") with Petrichor Opportunities Fund I LP (the "Investor") in connection with the issuance of up to $45,000 of senior secured floating rate convertible notes (the "Notes"), issuable in multiple tranches (the "Note Financing"). On August 19, 2022, the Company closed the initial tranche of $5,000 (the "First Closing Note") which has an initial conversion price equal to $8.11 per share, which was calculated based on a 20% premium of the 5-day volume weighted average price of the Company's common shares as traded on the Nasdaq Capital Market (the "VWAP") immediately prior to the announcement of the SPA. In connection with the first closing, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of $5,000.

On September 23, 2022, the Company closed the second tranche of the Note Financing in the amount of $20,000 the "Second Closing Note"), which has an initial conversion price equal to $7.89 per share, which was calculated based on a 20% premium of the 5-day VWAP immediately prior to September 20, 2022, which was the date the Company obtained FDA approval of PEDMARK®.

Subsequent to the funding of the Second Closing Note, and before December 31, 2023, the Company may draw up to $20,000 of additional financing under the SPA, in one or more tranches of $10,000 upon mutual agreement of the Company and the Investor (the "Subsequent Closing Notes"). The Subsequent Closing Notes will be convertible at a price per share equal to $7.89 per share, which price is calculated on the same basis as for the Second Closing Note.

A commitment fee of 2.0% of the Notes was payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase approximately 0.05 Fennec common shares ("First Closing Warrant") and half was payable in cash or warrants of approximately 0.05 Fennec common shares ("Second Closing Warrant"), at the Company's election, on the second closing. The warrants are exercisable at a price per share of $8.11 and will have a term of five years from the date of the grant. The Company elected to have all the commitment fee of the Notes payable in warrants.

The Company believes current funds, which include funds from the First Closing Note and the Second Closing Note, provide sufficient funding for the Company to carry out its planned activities, including the continuation of commercialization efforts of PEDMARK® in the United States and preparation for commercialization of PEDMARK® outside of the United States, for at least the next twelve months.

Fennec Pharmaceuticals Inc.
Notes to the Unaudited Interim Condensed Consolidated Financial Statements
(U.S. dollars and shares in thousands, except per share information)

2. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with US GAAP and are the responsibility of the Company's management. These unaudited interim condensed consolidated financial statements do not include all of the information and notes required by US GAAP for annual financial statements. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited condensed consolidated financial statements and notes filed with the Securities and Exchange Commission ("SEC") in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. The Company's accounting policies are consistent with those presented in the audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2022. These unaudited interim condensed consolidated financial statements have been prepared in U.S. dollars. All amounts presented are in thousands except for per share amounts. The results of operations for the three and nine months ended September 30, 2023, are not necessarily indicative of results to be expected for the full fiscal year.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expense during the reporting period. Significant estimates include product sales discounts and allowances, allowance against trade receivables, measurement of stock-based compensation and estimates of the Company's capital requirement over the next twelve months from the date of issuance of the consolidated financial statements. Actual results could differ from those estimates.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment principally in the United States. As of September 30, 2023, the Company had an operating lease in Ireland. This is the only asset located outside of the United States.

Stock-Based Compensation

Under the Company's stock-based compensation programs, the Company periodically grants stock options and restricted stock units to employees, directors, and consultants. The fair value of each award is recognized in the Company's statements of operations over the requisite service period for such award.

The Company uses the Black-Scholes option pricing model to value stock option awards without market conditions, which requires the Company to make certain assumptions regarding the expected volatility of its common stock price, the expected term of the option grants, the risk-free interest rate and the dividend yield with respect to its common stock. The Company calculates volatility using its historical stock price data. Due to the lack of the Company's own historical data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the Company's stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate used for each grant is based on the United States Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and, at present, has no intention to pay cash dividends.

Fennec Pharmaceuticals Inc.
Notes to the Unaudited Interim Condensed Consolidated Financial Statements
(U.S. dollars and shares in thousands, except per share information)

Inventory

Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Capitalized costs of inventories mainly include third party manufacturing, logistics and distribution costs. The Company assesses the recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories. The manufacturing costs for PEDMARK® prior to regulatory approval were not capitalized as inventory but were expensed as research and development costs. The Company expensed pre-launch inventory as it could not reasonably anticipate FDA approval of PEDMARK®.

Revenue Recognition

Under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company determines it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation(s). As part of the accounting for these arrangements, the Company must make significant judgments, including identifying performance obligations in the contract and estimating the amount of variable consideration to include in the transaction price.

Net Product Revenue

On September 20, 2022, the FDA approved PEDMARK® in the United States to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. PEDMARK® became commercially available in the United States on October 17, 2022. PEDMARK® is the Company's first commercial product. The Company sells its product through the following specialty distributors: Amerisource Specialty Distribution ("ASD"), McKesson Plasma and Biologics, McKesson Specialty, and Cardinal Health Specialty (collectively the "Customers" and each a "Customer"). Further, the Company sells directly to other customers without the use of specialty distributors. These Customers subsequently resell the Company's products to health care providers and patients. In addition to distribution agreements with Customers, the Company enters arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products. Revenues from product sales are recognized when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Customer. The amount of revenue recognized is net of these discounts in an amount equal to the cash expected to be collected.

Product Sales Discounts and Allowances

The Company records revenues from product sales at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established primarily from discounts, chargebacks, rebates, co-pay assistance, returns and other allowances that are offered within contracts between the Company and its Customers, health care providers, payors and other indirect customers relating to the sales of its products. These reserves are based on the amounts to be claimed on the related sales and are classified as a contra-asset or a current liability. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, forecasted Customer buying and payment patterns, and the Company's historical experience that will develop over time as PEDMARK® is the Company's first commercial product. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of its contracts. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it

is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenues and earnings in the period such variances become known.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty distributor. Contracted customers, which currently consist of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back to the Company the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by its contracted customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales by the specialty distributor to its contracted customers.

Discounts for Prompt Payment: Customers receive a discount of 0.65% for prompt payment. The Company expects its Customers will earn 100% of their prompt payment discounts and, therefore, the Company deducts the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and other government programs. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. The Company's estimates for the expected utilization of rebates are based on Customer and payor data received from the specialty distributors and historical utilization rates that will develop over time, as PEDMARK® is the Company's first commercial product. Rebates are generally invoiced by the payor and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to the Customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust its accruals, which would affect net product revenues in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The Company accrues a liability for co-payment assistance based on actual program participation and estimates of program redemption using Customer data provided by the third party that administers the copay program. If actual program redemption varies from estimates, the Company may need to adjust its accruals, which would affect net product revenues in the period of adjustment.

Other Customer Credits: The Company pays fees to certain of its Customers for account management, data management and other administrative services. To the extent the services received are distinct from the sale of products to its Customers, the Company classifies these payments in selling and marketing, general and administrative expenses in its Condensed Consolidated Statements of Operations.

The following table summarizes net product revenues for PEDMARK® in the United States and abroad earned during the three and nine months ended September 30, 2023 and 2022, respectively:

	Three Months Ended		Nine Months Ended	
In thousands	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Product revenues:				
Gross product revenues	$ 6,919	$ —	$ 12,525	$ —
Discounts and allowances	(404)	—	(1,008)	—
Net product revenues	$ 6,515	$ —	$ 11,517	$ —

Fennec Pharmaceuticals Inc.
Notes to the Unaudited Interim Condensed Consolidated Financial Statements
(U.S. dollars and shares in thousands, except per share information)

The following table summarizes the percentage of total product revenues for PEDMARK® in the United States and abroad by Customers who individually accounted for 10% or more of total product revenues earned in the three and nine months ended September 30, 2023, and 2022, respectively:

	Three Months Ended		Nine Months Ended	
Specialty Distributors	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
ASD	16 %	— %	24 %	—
McKesson	19	—	16	—
Subtotal-Specialty Distributors	35	—	40	—
Direct Customers	65	—	60	—
	100 %	— %	100 %	—

The activities and ending allowance balances for each significant category of discounts and allowances for PEDMARK® (which constitute variable consideration) for the nine months ended September 30, 2023, was as follows:

In thousands	Chargebacks, Discounts for Prompt pay and Other allowances	Rebates, Customer Fees/Credits and Co-Pay Assistance	Totals
Balance at December 31, 2022	$ 71	$ 163	$ 234
Provision related to sales made in:			
Current period	116	117	233
Prior periods	—	—	—
Payments and customer credits issued	(31)	(66)	(97)
Balance at March 31, 2023	$ 156	$ 214	$ 370
Provision related to sales made in:	246	148	394
Current period	—	—	—
Prior periods	—	—	—
Payments and customer credits issued	(193)	(124)	(317)
Balance at June 30, 2023	$ 209	$ 238	$ 447
Provision related to sales made in:			
Current period	334	180	514
Prior periods	—	—	—
Payments and customer credits issued	(307)	(71)	(378)
Balance at September 30, 2023	$ 236	$ 347	$ 583

The allowances for chargebacks, fees due to Customers, rebates and discounts for prompt payment are recorded as a contra-asset to accounts receivable, while Medicaid rebates and return allowances are in accrued liabilities in the accompanying Condensed Consolidated Balance Sheets.

Trade Receivables

The Company records gross trade receivables at the time of product sale to its Customers. Amounts estimated for the associated chargebacks, cash discounts for prompt payment and any allowances for credit losses are booked as a reserve against accounts receivable and reduction of revenue. The Company determines its allowance methodology by pooling receivable balances at the Customer level. The Company considers various factors, including loss history, individual credit risk associated to each Customer, and the current and future condition of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk

characteristics of such a Customer. The Customers are mainly specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low. It is the policy of the Company to reserve 1% of its net sales to non-specialty distributors, as such the Company had an immaterial balance in allowance for doubtful accounts as of September 30, 2023.

Cost of Products Sold

Cost of products sold is related to the Company's product revenues for PEDMARK® and consists primarily of product production costs associated with finished goods inventory and royalties (1% of net sales) the Company is required to pay to Oregon Health & Science University ("OHSU") on all net sales of PEDMARK®. The cost of products sold also consists of shipping and other third party logistics and distribution costs for PEDMARK®. The Company considered regulatory approval of PEDMARK® to be uncertain and product manufactured prior to regulatory approval could not have been sold unless regulatory approval was obtained. As such, the manufacturing costs for PEDMARK® incurred prior to regulatory approval were not capitalized as inventory but were expensed as research and development costs. After FDA approval in September 2022, the Company had various lots of PEDMARK® in various stages of production in connection with the product launch. As of September 30, 2023, the Company capitalized approximately $1.8 million of costs as inventory on the Condensed Consolidated Balance Sheet. Of the items capitalized, $0.1 million was capitalized as raw materials, $0.9 million was capitalized as work in process, $0.8 million was capitalized into finished goods, with $0.6 million being reclassified to cost of products sold.

Cash and Cash Equivalents

Cash equivalents consist of highly liquid investments with original maturities at the date of purchase of three months or less. The Company places its cash and cash equivalents in investments held by highly rated financial institutions in accordance with its investment policy designed to protect the principal investment. At September 30, 2023, the Company had $12,399 in cash, savings and money market accounts ($23,774 at December 31, 2022). At September 30, 2023, the Company held $2,007 in cash of which $488 (as presented in U.S. dollars) was in Canadian dollars ($34 at December 31, 2022 as presented in U.S. dollars). At September 30, 2023, the Company held $10,392 in money market investments. Money market investments typically have minimal risks. While the Company has not experienced any loss or write-down of its money market investments, the amounts it holds in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

Financial Instruments

Financial instruments recognized on the balance sheets at September 30, 2023 and December 31, 2022 consist of cash and cash equivalents, accounts receivable, accounts payable and term loans, the carrying values of which approximate fair value due to their relatively short time to maturity or interest rates that approximate market interest rates. The Company does not hold or issue financial instruments for trading.

The Company's investment policy is to manage investments to achieve, in the order of importance, the financial objectives of preservation of principal, liquidity and return on investment. Investments, when made, are made in U.S. or Canadian bank securities, commercial paper of U.S. or Canadian industrial companies, utilities, financial institutions and consumer loan companies, and securities of foreign banks provided the obligations are guaranteed or carry ratings appropriate to the policy. Securities must have a minimum Dun & Bradstreet rating of A for bonds or R1 low for commercial paper.

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The policy risks are primarily the opportunity cost of the conservative nature of the allowable investments. Until the company is cash flow positive from operations, the Company has chosen to avoid investments of a trading or speculative nature.

Research and Development Costs and Investment Tax Credits

Research costs, including employee compensation, laboratory fees, lab supplies, and research and testing performed under contract by third parties, are expensed as incurred. Development costs, including drug substance costs, clinical study expenses and regulatory expenses are expensed as incurred.

Investment tax credits, which are earned as a result of qualifying research and development expenditures, are recognized when the expenditures are made and their realization is reasonably assured. They are applied to reduce related capital costs and research and development expenses in the year recognized.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, and accounts receivable. The Company maintains deposits in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the high credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument.

The Company's trade receivables include amounts billed to Customers for product sales of PEDMARK®. The Customers are a limited group of specialty distributors and select customers abroad, with substantial financial resources, and accordingly, the Company considers the risk of potential credit losses to be low.

Income Taxes

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of September 30, 2023, we maintained a full valuation allowance against our deferred tax assets.

The provisions of the FASB ASC 740-10, Uncertainty in Income Taxes, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position.

Foreign Currency Transactions

The U.S. dollar is the functional currency for the Company's consolidated operations. All gains and losses from currency transactions are included in results of operations.

New Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments." This ASU replaces the incurred loss impairment methodology in current US GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information for credit loss estimates on certain types of financial instruments, including trade receivables. In addition, new disclosures are required. The ASU, as subsequently amended, is effective for the Company for fiscal years

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beginning after December 15, 2022, as the Company is a smaller reporting company as defined in Item 10(f)(1) of Regulation S-K. We adopted ASU 2016-13 on January 1, 2023. Based on the composition of the Company's accounts receivable, the adoption of this standard did not have a material impact on the Company's consolidated financial statements or disclosures. Specifically, the Company's estimate of expected credit losses as of September 30, 2023, using its expected credit loss evaluation process, resulted in no adjustments to the provision for credit losses and no cumulative effect adjustment to accumulated deficit on the adoption date of the standard.

In July 2023, the FASB issued Accounting Standards Update ("ASU") 2023-03 to amend various SEC paragraphs in the Accounting Standards Codification to primarily reflect the issuance of SEC Staff Accounting Bulletin No. 120. ASU No. 2023-03, "Presentation of Financial Statements (Topic 205), Income Statement-Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation-Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280-General Revision of Regulation S-X: Income or Loss Applicable to Common Stock." ASU 2023-03 amends the ASC for SEC updates pursuant to SEC Staff Accounting Bulletin No. 120; SEC Staff Announcement at the March 24, 2022 Emerging Issues Task Force ("EITF") Meeting; and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 - General Revision of Regulation S-X: Income or Loss Applicable to Common Stock. These updates were immediately effective and did not have a material impact on our financial statements.

In October 2023, the FASB issued Accounting Standards Update ("ASU") 2023-06 to amend various SEC paragraphs in the Accounting Standards Codification to primarily reflect SEC Release No. 33-10532, Disclosure Update and Simplification. ASU 2023-06 amends disclosure guidance over an entity's accounting policy related to derivative instruments, material prior period adjustments upon a change in a reporting entity, earnings-per-share, encumbered assets, unused lines of credit and unfunded commitments, and liquidation preferences of preferred stock. The amendments are effective prospectively on the date each individual amendment is effectively removed from Regulation S-X or Regulation S-K.

3. Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted net loss per share is computed using the same method, except the weighted average number of common shares outstanding includes convertible debentures, stock options and warrants, if dilutive, as determined using the if-converted method and treasury methods. Accordingly, warrants to purchase 0.2 million of our common shares and options to purchase 5.0 million of our common shares at September 30, 2023, were not included in loss per share. Such instruments would have an antidilutive effect. During the same period in 2022, warrants to purchase 0.04 million of our common shares and options to purchase 4.3 million common shares were excluded from the computation of loss per share as their inclusion would have been anti dilutive

The following outstanding options and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2023	2022
Options to purchase common shares	5,005	4,466
Warrants to purchase common shares	150	150

4. Stockholders' Equity

Authorized capital stock

The Company's authorized capital stock consists of an unlimited number of common shares, no par value per share.

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Warrants to Purchase Common Stock

During the three and nine months ended September 30, 2023 and 2022, there were no warrants issued or exercised. The company has 150 outstanding warrants have a weighted average life of 4.30 years, and a weighted average strike price of $7.79, on September 30, 2023.

Equity Incentive Plan

The Compensation Committee of the Board of Directors administers the Company's equity incentive plan (the "Plan"). The Compensation Committee designates eligible participants to be included under the Plan and approves the number of equity instruments to be granted from time to time under the Plan. Currently, the maximum number of equity instruments issuable under the Plan, together with the Company's prior stock option plan, is twenty-five percent (25%) of the total number of issued and outstanding common shares. Based upon the current shares outstanding, a maximum of 6,658 shares of common stock are authorized for issuance pursuant to stock options or other equity awards granted under the Plan. For all options issued under the Plan, the exercise price is the fair value of the underlying shares on the date of grant. All options vest within three years or less and are exercisable for a period of ten years from the date of grant. The Plan allows the issuance of Canadian and U.S. dollar grants. The table below outlines recognized contractor and employee expense from equity awards for the three and nine month periods ended September 30, 2023 and 2022.

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Contractor options expense recognized	$ —	$ 34	$ —	$ 103
Employee options expense recognized	865	1,853	4,497	3,260
Total option expense recognized	**$ 865**	**$ 1,887**	**$ 4,497**	**$ 3,363**

Stock Option Activity

The following is a summary of option activity for the three and nine months ended September 30, 2023 for stock options denominated in U.S. dollars.

Options	Number of Options (thousands)	Weighted-Average Exercise Price $USD
Outstanding at December 31, 2022	4,539	$ 5.13
Granted	580	8.12
Exercised	(49)	4.36
Forfeited	(38)	6.98
Outstanding at March 31, 2023	**5,032**	**5.43**
Granted	125	8.80
Exercised	(95)	5.60
Forfeited	(175)	7.51
Outstanding at June 30, 2023	**4,887**	$ **5.77**
Granted	370	7.88
Exercised	(92)	2.34
Forfeited	(160)	7.35
Outstanding at September 30, 2023	**5,005**	$ **5.94**

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Of the 5,005 U.S. denominated options granted and outstanding at September 30, 2023, 3,932 are fully vested and exercisable.

The value of options issued was estimated using the Black-Scholes option pricing model using the assumptions in the table below. The expected volatility was determined using historical volatility of our common shares based on the expected term of the award.

Black-Scholes Model Assumptions	Valuation Assumptions September 30, 2023
Expected dividend	0.00%
Risk free rate	3.56 - 5.12%
Expected volatility	49 - 77%
Expected life	1.5 - 6.0 years

Restricted Share Units Activity

The Plan allows for the issuance of restricted share units ("RSUs"). The following is a summary of RSU activity for the three and nine months ended September 30, 2023. During the three and nine months ended September 30, 2023, there were 32 and 36 RSU's released from restriction, respectively. During the three and nine months ended September 30, 2023, there were 84 and 101 RSUs forfeited by departing employees. RSUs vesting vary from one to three years.

RSUs Current Year	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2022	35
Awarded	264
Released	(1)
Outstanding at March 31, 2023	298
Awarded	98
Released	(3)
Forfeited	(17)
Outstanding at June 30, 2023	376
Awarded	—
Released	(32)
Forfeited	(84)
Outstanding at September 30, 2023	**260**

The value of RSUs issued was estimated using the share price on the date of the award multiplied by the number of common shares granted.

5. Fair Value Measurements

The Company has adopted ASC 820, the Fair Value Measurements and Disclosure Topic of the FASB. This Topic applies to certain assets and liabilities that are being measured and reported on a fair value basis. The Fair Value Measurements Topic defines fair value, establishes a framework for measuring fair value in accordance with US GAAP, and expands disclosure about fair value measurements. This Topic enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information

used to determine fair values. The Topic requires that financial assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.
Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.
Level 3: Unobservable inputs that are not corroborated by market data.

	Fair Value Measurement at September 30, 2023 and December 31, 2022 (in thousands)									
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2023	2022	2023	2022	2023	2022	2023	2022
Assets								
Cash and cash equivalents	$ 2,007 (1)	$ 307 (1)	$ 10,392	$ 23,467	$ —	$ —	$ 12,399	$ 23,774
Processa common shares	$ 13 (2)	$ 56 (2)	$ —	$ —	$ —	$ —	$ 13	$ 56

(1) The Company held approximately $2,007 in cash as of September 30, 2023, of which approximately $488 was in Canadian funds (translated into U.S. dollars). As of December 31, 2022, the Company held approximately $307 in cash of which approximately $33 was in Canadian funds (translated into U.S. dollars).
(2) The Company holds 51 unrestricted common shares of Processa Pharmaceuticals, Inc. (NASDAQ:PCSA), which it received as part of a royalty arrangement in 2020.

6. Commitments and Contingencies

Oregon Health & Science University Agreement

On February 20, 2013, we entered into an exclusive license agreement with Oregon Health & Science University (“OHSU”) for exclusive worldwide license rights to intellectual property directed to thiol-based compounds, including PEDMARK®, and their use in oncology (the “OHSU Agreement”). OHSU will receive certain milestone payments, royalty on net sales for licensed products and a royalty on any consideration received from sublicensing of the licensed technology.

On May 18, 2015, we negotiated an amendment (“Amendment 1”) to the OHSU Agreement, which expands Fennec’s exclusive license to include the use of N-acetylcysteine as a standalone therapy and/or in combination with sodium thiosulfate for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments in the OHSU Agreement including but not limited to the royalty rate on net sales for licensed products, royalty rate from sublicensing of the licensed technology and the fee payable upon the regulatory approval of a licensed product.

The term of the OHSU Agreement as amended by Amendment 1 expires on the date of the last to expire claim(s) covered in the patents licensed to Fennec or 8 years, whichever is later. In the event a licensed product obtains regulatory approval and is covered by the Orphan Drug Designation, the parties will in good faith amend the term of the agreement. PEDMARK® is currently protected by methods of use patent that the Company exclusively licensed from OHSU that expire in the United States in 2038. The OHSU Agreement is terminable by either Fennec or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. Fennec also has the right to terminate the OHSU Agreement at any time upon 60 days prior written notice and payment of all fees due to OHSU under the OHSU Agreement.

Securities Class Action Suit

Chapman v. Fennec Pharmaceuticals Inc., et al.

On September 3, 2020, plaintiff Jim Chapman filed a putative federal securities class action lawsuit against the Company, our Chief Executive Officer, Rostislav Raykov, and Chief Financial Officer, Robert Andrade, in the United States District

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Court for the Middle District of North Carolina, captioned *Chapman v. Fennec Pharmaceuticals Inc., et al.*, Case No. 1:20-cv-00812. The complaint alleged that prior to our August 10, 2020 receipt of a CRL from the FDA concerning our NDA for PEDMARK®, defendants made materially false or misleading statements and failed to disclose material facts about our third-party PEDMARK® product manufacturing facility and the impact the facility would have on regulatory approval for PEDMARK®. On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our Board of Directors as defendants, asserted a putative class period from December 20, 2018 through August 10, 2020, made allegations similar to those in the original complaint, claimed that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, and sought an unspecified amount of compensatory damages and attorneys' fees and costs.

On March 3, 2021, defendants filed a motion to dismiss the amended complaint. On April 2, 2021, lead plaintiff filed an opposition to the motion to dismiss. On April 16, 2021, defendants filed a reply in support of the motion to dismiss, and on December 16, 2021, the Magistrate Judge entered an order recommending that defendants' motion to dismiss be granted in its entirety. On January 24, 2022, lead plaintiff filed objections to the Magistrate Judge's recommendation, and defendants filed their response on February 3, 2022. On March 2, 2022, the U.S. District Court Judge adopted the Magistrate Judge's order and recommendation and entered an order and judgment dismissing the amended complaint with prejudice.

On March 30, 2022, lead plaintiff filed a motion for post judgment relief, seeking leave to file a second amended complaint. In his proposed second amended complaint, lead plaintiff sought to add allegations stemming from the receipt of a second CRL following our resubmission of our NDA for PEDMARK®, which we received on November 29, 2021, among other things. Defendants filed an opposition to plaintiff's motion for post judgment relief on April 20, 2022. On May 4, 2022, lead plaintiff submitted a reply in support of his motion. On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it has approved PEDMARK®. On October 18, 2022, lead plaintiff filed his opposition to request for judicial notice. On October 21, 2022, defendants filed a reply in support of the request for judicial notice. On February 15, 2023, the Magistrate Judge recommended the motion for post judgment relief be denied. Lead plaintiff filed no timely objection to the recommendation, and on March 2, 2023, the U.S. District Court Judge issued an order adopting the Magistrate Judge's recommendation, denying the motion for post judgment relief, and entering judgment for defendants. Lead plaintiff had until April 3, 2023 to file a notice of appeal and did not file a notice of appeal. The case is now closed.

Fisher v. Fennec Pharmaceuticals Inc. et al.

On February 9, 2022, plaintiff Jeffrey D. Fisher filed a putative federal securities class action lawsuit against the Company and our CEO and CFO in the United States District Court for the Middle District of North Carolina, captioned *Fisher v. Fennec Pharmaceuticals Inc., et al.*, Case No. 1:22-cv-00115. The complaint asserted a putative class period from May 28, 2021 through November 28, 2021, and alleged that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by making materially false and misleading statements or omissions regarding the status of our third-party PEDMARK® product manufacturing facility, the facility's compliance with cGMP, and the impact its status and compliance would have on regulatory approval for PEDMARK® in the period leading up to the Company's November 29, 2021 receipt of a CRL for a subsequent NDA for PEDMARK®. The complaint sought an unspecified amount of damages and attorneys' fees and costs. On April 11, 2022, plaintiff Jeffrey D. Fisher filed a motion to be appointed lead plaintiff and represent the putative class and on May 9, 2022, the court appointed him as lead plaintiff.

On June 23, 2022, lead plaintiff filed an amended complaint. The amended complaint asserted the same putative class period from May 28, 2021 through November 28, 2021, was brought against the same defendants and made allegations similar to those in the original complaint. On August 5, 2022, defendants filed a motion to dismiss the amended complaint. On August 26, 2022, lead plaintiff filed an opposition to the motion to dismiss. On September 9, 2022, defendants filed a reply in support of the motion to dismiss.

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On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it approved PEDMARK®. On September 30, 2022, lead plaintiff filed an opposition to the request for judicial notice. On October 6, 2022, defendants filed a reply in support of the request for judicial notice. On October 12, 2022, the U.S. District Court Judge issued a memorandum opinion and order dismissing the amended complaint in its entirety and with prejudice, and on October 14, 2022, entered judgment. Lead plaintiff had until November 14, 2022 to file a notice of appeal and did not file a notice of appeal. The case is now closed.

Hope Medical Enterprises, Inc. Inter Partes Review Challenges

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00123) with the Patent Trial and Appeal Board ("PTAB") of the USPTO to invalidate U.S. Patent No. 10,596,190 (the "'190 Patent"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using PEDMARK®. The '190 Patent was issued on March 24, 2020. On December 5, 2022, a Fennec filed a Motion to Amend the single claim of the '190 Patent focing on the treatment of medulloblastoma. On April 18, 2023, the PTAB invalidated the only claim of the'190 Patent. The final written decision became effective June 20, 2023. The '190 Patent was previously listed in the United States Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"). In light of PTAB's final written decision on the invalidity of the '190 Patent, we requested that the FDA remove the '190 Patent from the Orange Book. Two United States patent applications claiming priority through the '190 Patent remain pending at the United States Patent and Trademark Office ("USPTO").

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00125) to invalidate our wholly owned U.S. Patent No. 10,792,363 (the "'363 Patent"), which relates to an anhydrous form of STS and its method of manufacture, which is the active pharmaceutical ingredient in the PEDMARK® product. The '363 Patent was issued October 6, 2020. In May 2022, the PTAB granted Hope's Petition to Institute the IPR against the '363 patent. During the '363 IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. Because the remaining claims in the '363 patent are directed to a method of manufacture, the '363 patent is not eligible for listing in the Orange Book. In September 2023, the PTAB issued a Final Written Decision in favor of Fennec and upholding the amended claim. Hope has until November 3, 2023 to request that PTAB reconsider the Final Written Decision, or alternatively, file an appeal of the Final Written Decision with the Court of Appeals for the Federal Circuit. If no further actions are taken, the '363 Patent as amended will remain in force.

The USPTO has now granted three additional U.S. patents that cover the PEDMARK® formulation, each of which have been listed in the U.S. FDA's "Orange Book" (U.S. Patent No. 11,291,728 (issued April 5, 2022), U.S. Patent No. 11,510,984 (issued November 29, 2022), and U.S. Patent No. 11,617,794 (issued April 4, 2023)), and additional United States patent applications from this family remain pending at the USPTO. We plan to vigorously defend our intellectual property rights to PEDMARK®. An invalidation of our patents covering PEDMARK® could have a material adverse effect on our ability to protect our rights in PEDMARK® beyond periods of marketing exclusivity for PEDMARK® in the United States under Orphan Drug Designation.

CIPLA ANDA Litigation

On December 1, 2022, we received a letter dated November 30, 2022, notifying us that CIPLA Ltd. and CIPLA USA ("CIPLA") submitted to the FDA an ANDA (ANDA No. 218028) for a generic version of PEDMARK® (sodium thiosulfate solution) that contains Paragraph IV Certifications on two of our patents covering PEDMARK®: the OHSU licensed '190 Patent, expiration date January 2038; and our US 11,291,728 Patent (the "'728 Patent"), expiration date July 2039. On January 6, 2023, we received a letter dated January 5, 2023, notifying us that CIPLA submitted to the FDA a Paragraph IV Certification on our newly issued US 11,510,984 Patent (the "'984 Patent"). These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for PEDMARK®. The certifications allege these patents are invalid or will not be infringed by the manufacture, use, or sale of CIPLA's sodium thiosulfate solution.

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Under the Food and Drug Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, after receipt of a valid Paragraph IV notice, the Company may bring a patent infringement suit in a federal district court against CIPLA within 45 days from the receipt of the Notice Letter and if such a suit is commenced within the 45-day period, the Company is entitled to a 30 month stay on the FDA's ability to give final approval to any proposed products that reference PEDMARK®. In addition to the 30-month stay, because we have received Orphan Drug Exclusivity, the FDA may not approve CIPLA's ANDA for at least 7 years from PEDMARK®'s FDA approval date of September 20, 2022.

On January 10, 2023, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:23-cv-00123), for infringement of the '190 Patent, the '728 Patent, and the '984 Patent. On April 20, 2023, we filed an Amended Complaint to assert infringement of the '728 patent and the '984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the "'793 Patent") covering the formulation of the PEDMARK® product, which was listed in the Orange Book on or around April 17, 2023, and has an expiration date of July 2039. On May 11, 2023, we received written notice of CIPLA's Paragraph IV Certification as to the '793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the '793 Patent is invalid, unenforceable, and/or will not be infringed by CIPLA's ANDA Product. On July 27, 2023, we filed a Second Amended Complaint to assert the '793 Patent. The suit is ongoing.

PEDMARQSI™ (EU Brand name for PEDMARK®) received European Commission approval in June 2023 and was granted 10 years of market exclusivity in Europe under Pediatric Use ("PUMA").

Executive Severance

In the event of Mr. Raykov's termination with the Company other than for cause, the Company will be obligated to pay him a one-time severance payment equal to twelve months of salary (currently $585). In the event of Mr. Andrade's termination with the Company other than for cause, the Company will be obligated to pay him a one-time severance payment equal to six months of salary (currently $212).

Leases

The Company has an operating lease in Research Triangle Park, North Carolina utilizing a small space within a commercial building. The operating lease has payments of $0.4 per month with no scheduled increases. This operating lease is terminable with 30 days' notice and has no penalties or contingent payments due.

On January 23, 2020, the Company entered into an Office Service Agreement (the "Office Service Agreement") with Regus to lease office space at in Hoboken, New Jersey. Per the terms of the Office Service Agreement, the monthly rent payments are $1. The Company was required to pay a security deposit of $2, which is the equivalent to two months of rent. The Office Service Agreement commenced on January 27, 2020, and terminated on July 31, 2020, thereafter the lease has been continuing on a month-to-month basis with either party being able to terminate the agreement by providing one months' advance written notice of termination.

On August 1, 2023, the Company entered into a second Office Service Agreement (the "Second Office Service Agreement") with Regus to lease office space in Dublin, Ireland. Per the terms of the Second Office Service Agreement, the monthly rent payments are $2. The Company was required to pay a security deposit of $5, which is the equivalent of two months rent. The Second Office Service Agreement commenced on August 1, 2023 and terminates on January 31, 2025, thereafter the lease may continue on a month-to-month basis with either party being able to terminate the agreement by providing one months' advance written notice of termination.

The Second Office Service Agreement does not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring the operating lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate consisting of the current prime rate plus 150 basis points for operating leases that

commenced after August 2023. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

	September 30, 2023
Remaining lease terms (in months)	16
Discount rate	10 %
Maturities of lease liabilities as of September 30, 2023 were as follows (in thousands):	
Year Ending December 31,	
2023 (remaining three months)	$ 6
2024	23
2025	2
	31
Less imputed interest	2
Total lease liabilities	$ 29
Current operating lease liabilities	$ 21
Non-current operating lease liabilities	8
Total lease liabilities	$ 29

7. Term Loans

On August 1, 2022, the Company entered into the SPA with the Investor in connection with the issuance of up to $45,000 of Notes, issuable in multiple tranches. On August 19, 2022, the Company closed the initial tranche of $5,000, which has an initial conversion price equal to $8.11 per share, which was calculated based on a 20% premium of the 5-day VWAP immediately prior to the announcement of the SPA. In connection with the first closing, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of $5,000. The Notes become due on the maturity date, which is August 19, 2027.

On September 23, 2022, the Company closed the second tranche of the Note Financing in the amount of $20,000, which has an initial conversion price equal to $7.89 per share, which was calculated based on a 20% premium of the 5-day VWAP immediately prior to the Second Closing Trigger.

Subsequent to the funding of the Second Closing Note, and before December 31, 2023, the Company may draw up to $20,000 of additional financing under the SPA, in one or more tranches of $10,000 upon mutual agreement of the Company and the Investor. The Subsequent Closing Notes will be convertible at a price per share equal to $7.89 per share, which price is calculated on the same basis as for the Second Closing Note.

A commitment fee of 2.0% of the Notes was payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase approximately 0.05 Fennec common shares and half was payable in cash or warrants of approximately 0.05 Fennec common shares, at our election, on the second closing. The Company chose to issue warrants to satisfy the payable on both the first and second closing. The warrants are exercisable at a price per share of $8.11 and both have a maturity date of August 19, 2027.

Cash interest on outstanding principal shall accrue at a rate of prime, plus 4.5% per annum, from the date of funding (12.75% at September 30, 2023 and 12% as of December 31, 2022). Cash interest is due on the first business day of each calendar quarter (“Interest Date”). In addition to cash interest, payment-in-kind (“PIK”) interest will commence on funding date and accrue at a rate of 3.5% per annum. PIK interest will stop accruing on August 24, 2024. Any accrued PIK interest

shall remain outstanding and be payable on each Interest Date and be added to the outstanding principal amount. The Company has accrued $0.71 in PIK interest and has classified the PIK interest in long-term liabilities.

The Notes are convertible into fully paid, non-assessable shares of the Company's common shares at any point after their issuance dates and before the maturity date. Any amount of the Notes may be converted into the Company's common shares so long as it does not create partial shares. The conversion rate is determined by dividing the conversion amount by the conversion price. Provisions of the SPA create legal, valid and enforceable liens on, and security interests in, all of the Company's and each of its subsidiaries assets.

Aggregate annual payments due on the SPA as of September 30, 2023 are as follows (in thousands):

Years Ending December 31,	Amount
2023	$ —
2024	—
2025	—
2026	—
2027	25,000
Payment in kind interest	937
Total future payments	25,937
Less: unamortized debt discount	(298)
Total term loan, net of debt discount	$ 25,639

In the event of default or change of control, all unpaid principal and all accrued and unpaid interest amounts (if any) become immediately due and payable. Events of default include, but are not limited to, a payment default, a material adverse change, and insolvency. The SPA facility is secured by all of the Company's assets, including all capital stock held by the Company.

Debt issuance costs of $175 were paid in cash for legal fees and to the Investor in 2022 and warrants valued at $441 were granted to the Investor to secure access to the SPA. These amounts were capitalized and are being amortized over the access period of the SPA. Upon closing on the First Closing Note and the Second Closing Note, the Company recorded a debt discount of $314, which was based on a pro-rata allocation of the issue costs to secure the SPA, reducing the capitalized amount by the same amount. The debt discount is being amortized over the life of the SPA.

8. Subsequent Events

Management has evaluated subsequent events through the date of this filing and concluded there are no events of significance which require disclosure**.**

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Caution Concerning Forward-Looking Statements

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 29, 2023 (the "Annual Report") and our unaudited interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (the "Quarterly Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to the Company's plans and strategy for its business, includes, and our officers and representatives may from time to time make, forward looking statements, within the meaning of the of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements can be identified by words such as "future," "anticipates," "believes," "estimates," "expects," "intends," "plans," "predicts," "seeks," "goals," "projects," "strategy," "likely," "will," "would," "could," "can," "may," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. As a result of many factors, including those factors set forth in Part I, Item 1A of the Annual Report under the heading "Risk Factors", our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

The following discussion should be read in conjunction with our Annual Report and the condensed consolidated financial statements and accompanying notes included elsewhere in this report.

Overview

We are a commercial-stage biopharmaceutical company focused on our only product PEDMARK®. On September 20, 2022, we received approval from the US Food and Drug Administration ("FDA") for PEDMARK® (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. This approval makes PEDMARK® the first and only treatment approved by the FDA in this area of unmet medical need. On October 17, 2022, we announced commercial availability of PEDMARK® in the U. S. In addition, in January 2023, PEDMARK was included in the National Comprehensive Cancer Network (NCCN) clinical practice guidelines for Adolescent and Young Adult (AYA) Oncology with a category 2A recommendation.

In June 2023, we received European Commission Marketing Authorization for PEDMARQSI™ (known as PEDMARK® in the U.S.) Further, the decision included the receipt of a Pediatric Use Marketing Authorization ("PUMA") in the European Union ("EU") with up to 10 years of data and market protection. The Company is currently preparing for an EU launch of PEDMARQSI™ in 2024.

In the U.S., we sell our product through an experienced field force including Regional Pediatric Oncology Specialists and medical science liaisons who are helping to educate the medical communities and patients about cisplatin induced ototoxicity and our programs supporting patient access to PEDMARK®. Now that we have obtained applicable regulatory approval to sell PEDMARK® in the U. S. and authorization from the European Commission Marketing Authorization for PEDMARQSI™ in the EU, we recognize there may still be a need to establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties, or other revenue.

Further, we have established Fennec HEARS™, a comprehensive single source program designed to connect PEDMARK® patients to both patient financial and product access support. The program offers assistance and resources, regardless of insurance type, that can address co-pays or lack of coverage when certain eligibility requirements are met. Fennec HEARS™ also provides access to care coordinators that can answer insurance questions about coverage for PEDMARK® and provide tips and resources for managing treatment.

We received Orphan Drug Exclusivity for PEMARK in January 2023, which provides seven years of market exclusivity from its FDA approval on September 20, 2022 until September 20, 2029. We currently have three patents listed for PEDMARK® in the FDA's Orange Book. In September 2022, the USPTO issued Patent No. 11,291,728 (the "US '728 Patent"), in December 2022, the USPTO issued Patent No. 11,510,984 ("US '984 Patent") and in April 2023, the USPTO issued Patent No. 11,671,793 ("US '793 Patent") that covers PEDMARK® pharmaceutical formulation. The US '728 Patent, US '984 Patent and US '793 Patent will expire in 2039. We are also pursuing additional patent applications in both the U.S. and internationally for PEDMARK®.

PEDMARK® Product Overview

PEDMARK® is the first and only therapy approved by the FDA indicated to reduce the risk of ototoxicity associated with cisplatin treatment in pediatric patients with localized, non-metastatic, solid tumors. Further, PEDMARQSI™, known as PEDMARK® in the U.S. was granted marketing authorization by the European Commission in June 2023. PEDMARK® 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 more than 10,000 children annually 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.

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.

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. 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.

Liquidity

We generated a net loss of approximately $13.4 million for the nine months ended September 30, 2023, and a net loss of $16.9 million for the same period in 2022. As of September 30, 2023, our accumulated deficit was approximately $216.6 million ($203.2 million at December 31, 2022). We believe that our cash and cash equivalents as of September 30, 2023, which totaled $12.4 million, cash from product sales, plus the remaining Petrichor Financing of $20 million in convertible notes subject to mutual agreement between us and Petrichor (see Note 1 and Note 7 to our unaudited interim condensed consolidated financial statements contained elsewhere in this Quarterly Report), will be sufficient to meet our cash requirements through at least the next twelve months. Our projections of our capital requirements are subject to substantial uncertainty, and more capital than we currently anticipate may be required thereafter. To finance our continuing operations,

we may need to raise substantial additional funds through either the sale of additional equity, the issuance of debt, the establishment of collaborations, the out-license or sale of certain aspects of our intellectual property portfolio or from other sources.

Our operating expenses will depend on many factors, including the progress of our commercialization efforts abroad and efficiency of our operations and current resources. Our research and development expenses, which include expenses associated with our clinical trials, drug manufacturing to support clinical programs, consulting fees, sponsored research costs, toxicology studies, license fees, milestone payments, and other fees and costs related to the commercialization of our product, will depend on the availability of financial resources, the results of our clinical trials, and any directives from regulatory agencies, which are difficult to predict. Our general and administration expenses include expenses associated with the compensation of employees, stock-based compensation, professional fees, which include legal fees, consulting fees, insurance and other administrative matters associated in support primarily of our commercialization of PEDMARK®. Our 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.

Results of Operations

Three months ended September 30, 2023 versus three months ended September 30, 2022:

In thousands of U.S. Dollars	Three Months Ended September 30, 2023	%	Three Months Ended September 30, 2022	%	Change
PEDMARK® product sales, net	6,515		—		6,515
Cost of product sales	(331)	5 %	—	— %	(331)
Gross profit	$ 6,184		$ —		$ 6,184
Operating expenses:					
Research and development	12	— %	846	11 %	(834)
Selling and marketing	3,384	47 %	—	— %	3,384
General and administration	3,805	53 %	7,053	89 %	(3,248)
Total operating expense	7,201	100 %	7,899	100 %	(698)
Loss from operations	(1,017)		(7,899)		6,882
Unrealized loss on securities	(13)		(27)		14
Amortization expense	(72)		(64)		(8)
Interest expense	(856)		(119)		(737)
Unrealized foreign exchange loss	(11)		(4)		(7)
Interest income	102		24		78
Net loss	$ (1,867)		$ (8,089)		$ 6,222

We reported net product sales for the three month period ended September 30, 2023 of $6,515 and gross profit of $6,184 after applying cost of product sales of $331. Research and development expenses decreased by $834 for the three months ended September 30, 2023, compared to the same period in 2022. Our research and development activities for this period 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 were $3,384 for the three months ended September 30, 2023. 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. General and administrative expenses decreased by $3,248 compared to the same period in 2022, which was primarily driven by a decrease of non-cash employee remuneration of $1,000 and a decrease in legal expense by $707 as well as a major difference relating to the allocation of sales and marketing expenses to G&A for the period ended September 30, 2022 as we did not launch product until Q4 of 2022.

Interest expense increased $737 compared to the same period in 2022. This increase is associated with higher interest rates and $20,000 more in funded debt than in the same period in 2022. Further, we hold shares of Processa (NASDAQ: PCSA)

which are marked to market each balance sheet date and unrealized gains or losses are recognized at that time. The value of the Processa shares held by the Company was down by $13 for the three month period ending September 30, 2023, as opposed to a decrease of $27 during the same period in 2022. Other losses were driven mainly by unrealized losses related to our foreign currency transactions. We have vendors that transact in Euros, Great British Pounds and Canadian Dollars. There was an increase of $7 in other losses for the three months ended September 30, 2023, compared to the same period in 2022. Amortization expense is also a non-cash expense and relates to amortization of the deferred issuance costs of the loan facilities with Petrichor. Amortization expense increased by $8 for the three months ended September 30, 2023 compared to the same period in 2022. Interest income was up $78 for the three months ended September 30, 2023, compared to the same period in 2022. This was driven mainly by higher interest rates for the three months ended September 30, 2023 compared to the same period in 2022.

Nine months ended September 30, 2023 versus nine months ended September 30, 2022:

In thousands of U.S. Dollars	Nine Months Ended September 30, 2023	%	Nine Months Ended September 30, 2022	%	Change
PEDMARK® product sales, net	$ 11,517		$ —		$ 11,517
Cost of product sales	(574)	5 %	—	— %	(574)
Gross profit	10,943		—		10,943
Operating expenses:					
Research and development	24	— %	3,414	21 %	(3,390)
Selling and marketing	8,255	38 %	—	— %	8,255
General and administration	13,617	62 %	13,040	79 %	577
Total operating expenses	21,896	100 %	16,454	100 %	5,442
Loss from operations	(10,953)		(16,454)		5,501
Unrealized loss on securities	(43)		(126)		83
Amortization expense	(217)		(79)		(138)
Interest expense	(2,479)		(234)		(2,245)
Unrealized foreign exchange loss	3		(6)		9
Interest income	326		42		284
Net loss	$ (13,363)		$ (16,857)		$ 3,494

We reported net product sales for the nine month period ended September 30, 2023 of $11,517 and gross profit of $10,943 after applying cost of product sales of $574. Research and development expenses decreased by $3,390 for the nine months ended September 30, 2023, compared to the same period in 2022. Research activities, since the launch of PEDMARK® have been limited to investigator initiated clinical trials. Selling and marketing expenses were $8,255 for the nine months ended September 30, 2023. 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. General and administrative expenses increased by $577 over the same period in 2022. This difference was primarily driven by an increase in non-cash equity compensation and higher wages in the amount of $1,448 for the nine months ended September 30, 2023 over the same period in 2022. For the nine months ended September 30, 2023, there was a decrease in legal expense of $399. The rest of the difference primarily relates to sales and marketing expenses being included in G&A in 2022 before product launch in Q4 of 2022.

The unrealized loss on our shares of Processa for the nine months ended on September 30, 2023 was $43, which is in contrast to the $126 loss for the same period in 2022. Foreign currency transaction gain was $3 for the nine months ended September 30, 2023 ($6 loss for same period in 2022). Amortization expense was $217 for the nine months ended September 30, 2023, compared to $79 for the same period in 2022. Our amortization expense relates to the capitalized debt issuance costs associated with the Petrichor notes. Interest expense increased $2,245 for the nine months ended September 30, 2023, over same period in 2022. We replaced the $5 million loan facility with Bridge Bank with a larger facility, $25 million, with Petrichor. We took on this convertible debt load in a rising interest rate environment. Interest income was $284 higher for the nine months ended September 30, 2023, compared to the same period in 2022. This was driven mainly by higher interest rates for the nine months ended September 30, 2023 compared to the same period in 2022.

Liquidity and Capital Resources

Selected Asset and Liability Data (thousands):	As of September 30, 2023	As of December 31, 2022
Cash and equivalents	$ 12,399	$ 23,774
Other current assets	6,547	2,954
Current liabilities	(3,913)	(4,608)
Working capital [(1)]	15,033	22,120
[(1)] [Current assets – current liabilities]		
Selected Equity:		
Common stock and additional paid in capital	204,789	199,388
Accumulated deficit	(216,563)	(203,200)
Stockholders' deficit	(10,531)	(2,569)

Cash and cash equivalents were $12,399 at September 30, 2023 and $23,774 at December 31, 2022. The decrease in cash and cash equivalents between September 30, 2023 and December 31, 2022 is the result of expenses related to our normal operations, offset by inflows of cash generated from net product sales of $11,517 and $969 from various option exercises. There was an increase of $3,593 in other current assets between December 31, 2022, and September 30, 2023.

Current liabilities decreased by $695 between December 31, 2022, and September 30, 2023. The decrease was driven mainly by an increase in accounts payable ($551), offset by a large decrease of $1,268 in accrued expenses.

Working capital decreased between December 31, 2022, and September 30, 2023, by $7,087. The decrease relates to a net cash inflow from product sales and various option exercises, offset by expenditures for operating activities for the nine months ended September 30, 2023.

The following table illustrates a summary of cash flow data for the nine month period ended September 30, 2023 and 2022:

Selected Cash Flow Data (dollars and shares in thousands)	Nine Months Ended September 30, 2023	2022
Net cash used in operating activities	$ (12,283)	$ (11,256)
Net cash provided by investing activities	—	—
Net cash provided by financing activities	908	19,908
Net cash flow	$ (11,375)	$ 8,652

Net cash used in operating activities for the nine months ended September 30, 2023 and 2022, primarily reflected a net loss of $13,363 and $16,857, respectively. The nine month losses were adjusted for the add back of non-cash items consisting of $4,497 and $3,363, respectively, in stock-based compensation expense, with unrealized loss on securities of $43 and $126, respectively, and amortization expense of $217 and $79, respectively, for the nine months ended September 30, 2023, and 2022. For the nine months ended September 30, 2023 there was an increase in other current assets of $3,593 and a decrease of $756 during the same period in 2022. For the nine months ended September 30, 2023, there was a net decrease in current liabilities of $696, with a net increase of $1,273 during that same period in 2022. Nine month negative cash flows from operating activities were $12,283 and $11,256, respectively, for the periods ended September 30, 2023 and 2022. Net cash provided by financing activities for the nine months ended September 30, 2023, were $908 and $19,908, respectively. Net cash flows from the nine month period ended September 30, 2023 and 2022, were negative $11,375, and positive $8,652, respectively.

We continue to pursue various strategic alternatives including collaborations with other pharmaceutical and biotechnology companies. Our projections of further capital requirements are subject to substantial uncertainty. Our working capital requirements may fluctuate in future periods depending upon numerous factors, including: our ability to obtain additional financial resources; our ability to enter into collaborations that provide us with up-front payments, milestones or other payments; progress or lack of progress in our preclinical studies or clinical trials; unfavorable toxicology in our clinical

programs; our drug substance requirements to support clinical programs; change in the focus, direction, or costs of our research and development programs; headcount expense; the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our patent claims; competitive and technological advances; the potential need to develop, acquire or license new technologies and products; our business development activities; new regulatory requirements implemented by regulatory authorities; the timing and outcome of any regulatory review process; and commercialization activities, if any.

Outstanding Share Information

Our outstanding share data as of September 30, 2023 and December 31, 2022 was as follows (in thousands):

Outstanding Share Type	September 30, 2023	December 31, 2022	Change
Common shares	26,633	26,361	272
Warrants	150	150	—
Stock options	5,005	4,539	466
Total	31,788	31,050	738

Financial Instruments

We invest excess cash and cash equivalents in high credit quality investments held by financial institutions in accordance with our investment policy designed to protect the principal investment. At September 30, 2023, we had approximately $2,007 in our cash accounts and $10,392 in savings and money market accounts. While we have never experienced any loss or write down of our money market investments since our inception, the amounts we hold in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

Our investment policy is to manage investments to achieve, in the order of importance, the financial objectives of preservation of principal, liquidity and return on investment. Investments may be made in U.S. or Canadian obligations and bank securities, commercial paper of U.S. or Canadian industrial companies, utilities, financial institutions and consumer loan companies, and securities of foreign banks provided the obligations are guaranteed or carry ratings appropriate to the policy. Securities must have a minimum Dun & Bradstreet rating of A for bonds or R1 low for commercial paper. The policy also provides for investment limits on concentrations of securities by issuer and maximum-weighted average time to maturity of twelve months. This policy applies to all of our financial resources. The policy risks are primarily the opportunity cost of the conservative nature of the allowable investments. Until we are cash flow positive from operations, we have chosen to avoid investments of a trading or speculative nature.

We classify fixed income investments with original maturities at the date of purchase greater than three months which mature at or less than twelve months as current. We carry investments at their fair value with unrealized gains and losses included in other comprehensive income (loss); however, we have not held any instruments that were classified as short-term investments during the periods presented in this Quarterly Report.

Off-Balance Sheet Arrangements

Since our inception, we have not had any material off-balance sheet arrangements.

Contractual Obligations and Commitments

None, other than the OHSU Agreement and lease agreements described in our unaudited interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report, and the severance amounts as disclosed in the Annual Report.

Critical Accounting Policies and Estimates

A summary of our critical accounting policies and use of estimates are presented in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operation” of our Annual Report. There have been no material changes to our critical accounting policies and use of estimates during the nine months ended September 30, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

(a) ***Evaluation of Disclosure Controls and Procedures***.

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Based on this evaluation at the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and our Chief Financial Officer, have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

(b) Changes in Internal Control over Financial Reporting.

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

For information about our legal proceedings, please see our Commitments and Contingencies footnote (Note 6) to our unaudited interim condensed consolidated financial statements included in Part 1. of this Quarterly Report**.**

Item 1A. Risk Factors.

Our Annual Report includes a detailed discussion of our risk factors under the heading “PART I, Item 1A – Risk Factors.” You should carefully consider the risk factors discussed in our Annual Report, as well as other information in this Quarterly Report. Any of these risks could cause our business, financial condition, results of operations and future growth prospects to suffer. We are not aware of any material changes from the risk factors previously disclosed.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On November 6, 2023, we issued a press release announcing our financial results for the quarter ended September 30, 2023. A copy of the news release is attached to this Quarterly Report as Exhibit 99.1. The press release 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 the press release.

Item 6. Exhibits

Exhibit No.	Description
31.1	Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
99.1	Press Release for Quarter Ended September 30, 2023 (filed herewith).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

SIGNATURES

Pursuant to requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Fennec Pharmaceuticals Inc.

Date: November 9, 2023

By: */s/ Rostislav Raykov*
Rostislav Raykov
Chief Executive Officer
(principal executive officer)

Date: November 9, 2023

By: */s/ Robert Andrade*
Robert Andrade
Chief Financial Officer
(principal financial and chief accounting officer)

Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Rostislav Raykov, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 of Fennec Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the unaudited interim condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

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

Exhibit 31.2

FENNEC PHARMACEUTICALS INC.
CERTIFICATION

I, Robert Andrade, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023, of Fennec Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the unaudited interim condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Fennec Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 (the "Report"), each of the undersigned, Rostislav Raykov, Chief Executive Officer of the Company, and Robert Andrade, Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2023

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

Date: November 9, 2023

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

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

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

~ Strong Commercial Uptake Underscoring Significant Unmet Medical Need ~

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

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

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

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

Financial Results for the third Quarter 2023

- **Net Sales** – The company recorded net product sales of $6.5 million in the third quarter of 2023 compared to net product sales of $3.3 million in the second quarter of 2023. The Company had gross profit of $6.2 million for the third quarter of 2023. The increase in sales reflects strong growth in new patient starts and account adoption.
- **Cash Position –** Cash and cash equivalents were $12.4 million on September 30, 2023. The decrease in cash and cash equivalents between September 30, 2023, and December 31, 2022, is the result of cash outlays for operating expenses related to the promotion and marketing of PEDMARK® and general and administrative expenses, which were offset by cash inflows primarily from product sales. We anticipate that our cash, cash equivalents and investment securities as of September 30, 2023, when coupled with PEDMARK revenue assumptions will be sufficient to fund our planned operations for at least the next twelve months.
- **Research and Development (R&D) Expenses** – Research and development expenses decreased by $0.8 million for the three months ended September 30, 2023, compared to the same period in 2022. The Company's research and development activities for the quarter ended September 30, 2023 consisted of costs associated with investigator initiated clinical trials. During the same period in 2022 and prior to approval of PEDMARK®, manufacturing costs pertaining to PEDMARK® were allocated to R&D expense in the period incurred, and following approval are reflected in inventory.

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

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

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

Q3 2023 CONFERENCE CALL INFORMATION

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

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

Financial Update

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements, which were prepared in accordance with U.S. generally accepted accounting principles. The complete unaudited condensed consolidated financial statements for the period ended September 30, 2023, and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

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

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

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

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

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

About Cisplatin-Induced Ototoxicity

Cisplatin and other platinum compounds are essential chemotherapeutic agents for the treatment of many pediatric malignancies. Unfortunately, platinum-based therapies can cause ototoxicity, or hearing loss, which is permanent, irreversible, and particularly harmful to the survivors of pediatric cancer.[i]

The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids or cochlear implants, which can be helpful for some, but do not reverse the hearing loss and can be costly over time.[ii] Infants and young children that are affected by ototoxicity at critical stages of development lack speech and language development and literacy, and older children and adolescents often lack social-emotional development and educational achievement.[iii]

PEDMARK® (sodium thiosulfate injection)

PEDMARK® is the first and only U.S. Food and Drug Administration (FDA) approved therapy indicated to reduce the risk of ototoxicity associated with cisplatin treatment in pediatric patients with localized, non-metastatic, solid tumors. It is a unique formulation of sodium thiosulfate in single-dose, ready-to-use vials for intravenous use in pediatric patients. PEDMARK is also the only therapeutic agent with proven efficacy and safety data with an established dosing paradigm, across two open-label, randomized Phase 3 clinical studies, the Clinical Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

In the U.S. and Europe, it is estimated that, annually, more than 10,000 children may receive platinum-based chemotherapy. The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult, and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. Infants and young children that suffer ototoxicity at critical stages of development lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

PEDMARK has been studied by co-operative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, COG ACCL0431 and SIOPEL 6. Both studies have been completed. The COG ACCL0431 protocol enrolled childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, medulloblastoma, and other solid tumors. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

Indications and Usage
PEDMARK® (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Limitations of Use
The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Important Safety Information
PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.

Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium levels at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.

Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m^2.

Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.

The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL 6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full Prescribing Information for PEDMARK® at: www.PEDMARK.com.

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® and Pedmarqsi™ to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission Marketing Authorization in June 2023 for Pedmarqsi. PEDMARK has received Orphan Drug Exclusivity in the U.S. for seven years of market protection and Pedmarqsi has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. Fennec has a license agreement with Oregon Health and Science University (OHSU) for exclusive worldwide license rights to intellectual property directed to sodium thiosulfate and its use for chemoprotection, including the reduction

of risk of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com.

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline, and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2022. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

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.