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, 2024
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	☐	Accelerated Filer	☐
Non-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 5, 2024, there were 27,432,234 of the registrant's common shares outstanding.

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Condensed Consolidated Balance Sheets
(U.S. Dollars and shares in thousands)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 40,320	$ 13,269
Accounts receivable, net	12,908	8,814
Prepaid expenses	3,066	2,575
Inventory	1,125	2,156
Other current assets	546	44
Total current assets	57,965	26,858
Non-current assets		
Other non-current assets, net of amortization	956	6
Total non-current assets	956	6
Total assets	$ 58,921	$ 26,864
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,867	$ 3,778
Accrued liabilities	3,313	3,754
Operating lease liability - current	7	21
Contract liability - current	248	—
Total current liabilities	7,435	7,553
Non-current liabilities		
Term loan	30,000	30,000
PIK interest	2,323	1,219
Debt discount	(227)	(288)
Contract liability - long-term	24,561	2
Total non-current liabilities	56,657	30,933
Total liabilities	64,092	38,486
Commitments and contingencies (Note 6)		
Stockholders' deficit:		
Common stock, no par value; unlimited shares authorized; 27,422 shares issued and outstanding (2023 - 27,027)	145,438	144,307
Additional paid-in capital	65,844	62,073
Accumulated deficit	(217,696)	(219,245)
Accumulated other comprehensive income	1,243	1,243
Total stockholders' deficit	(5,171)	(11,622)
Total liabilities and holders' deficit	$ 58,921	$ 26,864

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, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Revenue				
Product sales, net	$ 6,974	$ 6,515	$ 21,655	$ 11,517
Licensing revenue	—	—	17,958	—
Total revenue	6,974	6,515	39,613	11,517
Operating expenses:				
Cost of product sales	1,357	331	2,515	574
Research and development	97	12	257	24
Selling and marketing	4,601	3,384	14,482	8,255
General and administrative	6,121	3,805	18,857	13,617
Total operating expenses	12,176	7,532	36,111	22,470
(Loss) / Income from operations	(5,202)	(1,017)	3,502	(10,953)
Other (expense)/income				
Realized foreign exchange (loss)/gain	—	(11)	(55)	3
Amortization expense	(21)	(72)	(64)	(217)
Unrealized loss on securities	(3)	(13)	(14)	(43)
Interest income	516	102	1,283	326
Interest expense	(1,025)	(856)	(3,103)	(2,479)
Total other expense	(533)	(850)	(1,953)	(2,410)
Net (loss) / income	$ (5,735)	$ (1,867)	$ 1,549	$ (13,363)
Basic net (loss) / income per common share	$ (0.21)	$ (0.07)	$ 0.06	$ (0.50)
Diluted net (loss) / income per common share	$ (0.21)	$ (0.07)	$ 0.06	$ (0.50)
Weighted-average number of common shares outstanding basic	27,371	26,596	27,371	26,523
Weighted-average number of common shares outstanding diluted	27,371	26,596	28,015	26,523

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

Fennec Pharmaceuticals Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
Three and Nine Months Ended September 30, 2024, and 2023
(U.S. dollars and shares in thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity/(Deficit)
	Shares	Amount				
Balance at December 31, 2023	**27,027**	**$ 144,307**	**$ 62,073**	**$ (219,245)**	**$ 1,243**	**$ (11,622)**
Stock-based compensation - employees	—	—	1,191	—	—	1,191
Restricted stock release	3	—	(19)	—	—	(19)
Net income	—	—	—	12,837	—	12,837
Balance at March 31, 2024	**27,105**	**144,934**	**63,245**	**(206,408)**	**1,243**	**3,014**
Stock-based compensation - employees	—	—	925	—	—	925
Stock option exercise	147	347	—	—	—	347
Restricted stock release	77	—	(90)	—	—	(90)
Net loss	—	—	—	(5,553)	—	(5,553)
Balance at June 30, 2024	**27,329**	**145,281**	**64,080**	**(211,961)**	**1,243**	**(1,357)**
Stock-based compensation - employees	—	—	1,821	—	—	1,821
Stock option exercise	55	157	—	—	—	157
Restricted stock release	38	—	(57)	—	—	(57)
Net loss	—	—	—	(5,735)	—	(5,735)
Balance at September 30, 2024	**27,422**	**$ 145,438**	**$ 65,844**	**$ (217,696)**	**$ 1,243**	**$ (5,171)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity/(Deficit)
	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-based compensation - consultants	—	—	—	—	—	—
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-based compensation - consultants	—	—	—	—	—	—
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-based compensation - consultants	—	—	—	—	—	—
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)**

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, 2024	September 30, 2023
Cash flows provided by (used in):		
Operating activities:		
Net income/(loss)	$ 1,549	$ (13,363)
Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities:		
Inventory reserve	517	—
Allowance for doubtful accounts	3,604	
Amortization of debt discount	64	51
Loss on securities	14	43
Amortization of Norgine asset	774	—
Amortization of debt access fees	—	166
PIK interest	1,104	677
Stock-based compensation - employees	3,937	4,497
Changes in operating assets and liabilities:		
Accounts receivable	(7,698)	(2,980)
Prepaid expenses	(491)	523
Inventory	514	(1,179)
Other current assets	109	—
Accounts payable	89	551
Accrued liabilities	(441)	(1,269)
Contract liability - Norgine	24,809	—
Net cash provided by / (used in) operating activities	28,454	(12,283)
Financing activities:		
Issuance of shares, options exercise	504	969
Cash paid for taxes on restricted share release	(167)	(61)
Deferred costs	(1,740)	—
Net cash (used in) / provided by financing activities	(1,403)	908
Increase/(decrease) in cash and cash equivalents	27,051	(11,375)
Cash and cash equivalents - Beginning of period	13,269	23,774
Cash and cash equivalents - End of period	$ 40,320	$ 12,399
Supplemental disclosures of cash flow information:		
Non-cash investing and financing activities:		
Capitalized lease asset	$ 21	$ 29

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® in the U.S. and PEDMARQSI® the European branded name for PEDMARK® (collectively, "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 Limited 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-month period ended September 30, 2024, the Company earned a (loss)/income from operations of $(5,202) and $3,502 respectively. At September 30, 2024, it had an accumulated deficit of $217,696 and had experienced positive cash flows from operating activities during the nine months ended September 30, 2024, in the amount of $28,454.

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 on 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 dated August 1, 2022. In connection with the closing of the First Closing Note, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of $5,000.

On September 23, 2022, the Company closed on 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.

The SPA provided that subsequent to the funding of the Second Closing Note, and before December 31, 2023, the Company could 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, which was paid by the Company issuing the Investor warrants to purchase 110,996 of the Company's common shares (one half issued at the closing of the First Closing Note and the other half issued at the closing of the Second Closing Note).The warrants are exercisable at a price per share of $8.11 and have a term of five years from the date of the grant.

On December 4, 2023, the Company closed the third tranche of the Note Financing in the amount of $5,000 (the "Third Closing Note") which is convertible at a price equal to $7.89 per share, calculated as 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.

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

Also on December 4, 2023, the Company entered into a First Amendment to the Securities Purchase Agreement (the "SPA Amendment") with the Investor, which, among other things, extends the period that the Company may draw the remaining $15,000 under the SPA from December 31, 2023, to December 31, 2024. Subsequent draws are subject to mutual agreement of the Company and the Investor and will be represented by Notes that will also be convertible at a price equal to $7.89 per share.

On March 17, 2024, the Company announced it had entered into an exclusive licensing agreement with Norgine Pharma UK Limited ("Norgine") to commercialize PEDMARQSI® (EU brand name for PEDMARK) in Europe, New Zealand and Australia. The licensing agreement provided Fennec with approximately $43,200 up front and may provide Fennec with up to approximately $230,000 in milestone and royalty payments in the future. On July 26, 2024, Norgine and Fennec amended the exclusive licensing agreement. The amended agreement maintains all principal payment terms with the primary addition of Norgine assuming responsibility for packaging and labeling of PEDMARQSI®.

The Company believes current funds provide sufficient funding for the Company to carry out its planned activities, including the continuation of commercialization efforts of PEDMARK, for at least the next twelve months and into 2026.

These financial statements do not reflect the potentially material adjustments in the carrying values of assets and liabilities, the reported expenses, and the balance sheet classifications used, that would be necessary if the going concern assumption were not appropriate.

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, 2023. 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, 2023. 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.

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 revenue recognition, allowance against trade receivables, measurement of stock-based compensation and estimates of the Company's capital requirements 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. As of September 30, 2024, the Company had an operating lease in Ireland which is scheduled to terminate on January 31, 2025. This is the only asset currently located outside of the United States.

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

Stock-Based Compensation

Under the Company's stock-based compensation programs, the Company periodically grants stock options and restricted stock to employees, directors and consultants. The Company also issues shares under an employee stock purchase plan. 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.

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 to capitalize inventory costs for a product based on, among other factors, status of regulatory approval, 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 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, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

License Agreements

The Company generates revenue from license or similar agreements with pharmaceutical companies for the commercialization of its product. Such agreements may include the transfer of intellectual property rights in the form of licenses. Payments made by the customers may include non-refundable upfront fees, payments based upon the achievement of defined milestones, and royalties on sales of product.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon

transfer of control of the license. All other promised goods or services in the agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services where any additional consideration paid to the Company reflects their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as separate performance obligations.

Contingent milestones at contract inception are estimated at the amount which is not probable of a material reversal and included in the transaction price using the most likely amount method. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development or sales-based milestone payments that may not be subject to a material reversal and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

For arrangements that include sales-based royalties, including sales-based milestone payments, and a license of intellectual property that is deemed to be the predominant item to which the royalties relate, revenue is recognized at the later of when the related sales occur or when the performance obligation to which some or all of the royalties have been allocated has been satisfied (or partially satisfied).

Costs to Obtain Contract

As the majority of the Company's contracts are short-term in nature, sales commissions are generally expensed when incurred as the amortization period would have been less than one year. These costs are recorded within selling and marketing expenses in the condensed consolidated statements of operations. For contracts that extend beyond one year, the incremental expense recognition matches the recognition of related revenue.

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 on October 17, 2022. PEDMARK is the Company’s first and only commercial product. Certain specialty distributors of the Company subsequently resell the Company’s products to health care providers and patients. In addition to distribution agreements with these customers, the Company enters into 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.

Further, on March 17, 2024, the Company announced it had entered into an exclusive licensing agreement with Norgine to commercialize PEDMARQSI® (EU brand name for PEDMARK) in Europe, New Zealand and Australia.

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 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 and PEDMARQSI® (European branded product name) is the Company's first and only 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. 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 typically receive a small discount 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 and only 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.

Other Customer Credits: The Company pays fees to 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 expenses in its condensed consolidated statements of operations.

Distribution and Other Fees: The Company pays distribution and other fees to certain customers in connection with the sales of PEDMARK. The Company records distribution and other fees paid to its customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and the Company can reasonably estimate the fair value of the goods or services received. If both conditions are met, the Company records the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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 net product revenues for PEDMARK earned during the three and nine months ended September 30, 2024, and 2023, respectively:

	Three Months Ended		Nine Months Ended	
In thousands	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Product revenues:				
Gross product revenues	$ 7,986	$ 6,919	$ 27,008	$ 12,525
Discounts and allowances	(1,012)	(404)	(5,353)	(1,008)
Net product revenues	$ 6,974	$ 6,515	$ 21,655	$ 11,517

For the three and nine months ended September 30, 2024, the Company had one and four distributors that each represented more than 10% of net sales, respectively. For the three and nine months ended September 30, 2023, the Company had two distributors that each represented more than 10% of net sales.

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, 2024, were 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, 2023	$ 365	$ 430	$ 795
Provision related to sales made in:			
Current period	352	1,640	1,992
Prior periods	—	—	—
Payments and customer credits issued	(497)	(104)	(601)
Balance at March 31, 2024	$ 220	$ 1,966	$ 2,186
Provision related to sales made in:			
Current period	175	2,644	2,819
Prior periods	—	—	—
Payments and customer credits issued	(66)	(2,614)	(2,680)
Balance at June 30, 2024	$ 329	$ 1,996	$ 2,325
Provision related to sales made in:			
Current period	837	328	1,165
Prior periods	—	—	—
Payments and customer credits issued	(834)	(959)	(1,793)
Balance at September 30, 2024	$ 332	$ 1,365	$ 1,697

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. Customers in the United States are specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low. Sales to non-specialty distributors outside the United States have greater potential for losses. It is the policy of the Company to use a sliding scale to establish a reserve of its gross sales to non-specialty distributors, based on the aging category, in combination with management's specific review of each past due customer balance. The Company had a balance in allowance for credit losses of $4,971 as of September 30, 2024.

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 the Company is required to pay to Oregon Health & Science University ("OHSU") on all net sales of PEDMARK. 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 in the fourth quarter of 2022. As of September 30, 2024, the Company capitalized approximately $1,125 of costs as inventory on the condensed consolidated balance sheet. Of the items capitalized, $377 was capitalized as raw materials, $108 was capitalized as work in process, $640 was capitalized into finished goods.

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, 2024, the Company had $40,320 in cash, savings and money market accounts (13,269 at December 31, 2023). 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, 2024 and December 31, 2023 consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities 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.

The policy risks are primarily the opportunity cost of the conservative nature of the allowable investments. The Company has chosen to avoid investments of a trading or speculative nature to preserve cash.

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Common Shares and Warrants

As of September 30, 2024, the Company has 150 warrants with a weighted average strike price of $7.71 outstanding to purchase common shares that have a weighted average life of 3.30 years.

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 includes amounts billed to customers for product sales of PEDMARK. In the U.S., the customers are a limited group of specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low. The Company also sells to a select group of global distributors. These global distributors are established companies and although the Company regards credit losses with these distributors to be remote, it does recognize the potential for credit losses with this group.

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, 2024, we maintained a full valuation allowance against our deferred tax assets.

The provisions of the Financial Accounting Standards Board ("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 the results of operations.

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Net Income/(Loss) Per Share

Basic net income/(loss) per share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted net income/(loss) per share is computed using the same method, except the weighted average number of common shares outstanding includes convertible debentures, restricted stock units, stock options and warrants, if dilutive, as determined using the if-converted method and treasury methods. Accordingly, warrants to purchase 150 of our common shares, restricted share units to purchase 367 of our common shares and options to purchase 5,455 of our common shares at September 30, 2024, were not included in earnings per share. Such warrants, options and convertible notes would have an antidilutive effect. In 2023, warrants to purchase 150 of our common shares and options to purchase 5,005 common shares were excluded from the computation of loss per share as their inclusion would have been antidilutive.

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Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued amended guidance for improvements to reportable segment disclosures (ASU) No. 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," that requires a public entity disclose significant segment expenses regularly reviewed by the chief operating decision maker (CODM), including public entities with a single reportable segment. The amended guidance is effective for fiscal years beginning January 1, 2024, and interim periods beginning January 1, 2025 and should be applied on a retrospective basis. Early adoption is permitted. The Company is currently evaluating the effect the adoption of this ASU will have on its consolidated financial statements.

In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. The Company is currently evaluating the effect the adoption of this ASU will have on its consolidated financial statements.

On March 21, 2024, the FASB issued Accounting Standards Update (ASU) 2024-01, Compensation-Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards, which provides illustrative guidance to help entities determine whether profits interest and similar awards should be accounted for as share-based payment arrangements within the scope of FASB Accounting Standards Codification (FASB ASC) 718, Compensation-Stock Compensation. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. The Company believes that ASU 2024-01 will not have a material impact on the Company's condensed consolidated financial statements.

3. Net Income/(Loss) Per Share

Net income/(loss) per common share is presented under two formats: basic net income/(loss) per common share and diluted income/(loss) per common share. Basic net income/(loss) per common share is computed by dividing net income/(loss) attributable to common shareholders by the weighted average number of common shares outstanding during the period. Diluted income/(loss) per common share is computed by dividing net income/(loss) by the weighted average number of common shares outstanding during the period, plus the potentially dilutive impact of common shares equivalents (e.g. convertible debt, stock options and warrants). Dilutive common share equivalents consist of the incremental common shares issuable upon exercise of convertible debt, restricted stock units, stock options and warrants. The following table sets forth the computation of basic and diluted net income/(loss) per share (in thousands except per share data):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net (loss) / income	$ (5,735)	$ (1,867)	$ 1,549	$ (13,363)
Denominator:				
Weighted-average common shares, basic	27,371	26,596	27,371	26,523
Dilutive effect of stock options	—	—	620	—
Dilutive effect of warrants	—	—	24	—
Weighted-average common shares, diluted	27,371	26,596	28,015	26,523
Net loss per share, basic and diluted	**$** (0.21)	**$** (0.07)	**$** 0.06	**$** (0.50)

The following common stock equivalents, outstanding convertible debt, options and warrants were excluded from the computation of diluted net income/(loss) per share for the periods presented because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2024	2023
Options to purchase common shares	4,835	5,005
Warrants to purchase common shares	126	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.

Warrants to Purchase Common Stock

During the three and nine months ended September 30, 2024 and 2023, there were no warrants issued or exercised. Outstanding warrants have a weighted average life of 3.30 years on September 30, 2024. The following tables detail the Company's warrant activity for the three and nine months ended September 30, 2024, and 2023, respectively:

Investor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price $USD
Outstanding December 31, 2023	150	$ 7.71
Issued	—	—
Outstanding March 31, 2024	150	7.71
Issued	—	—
Outstanding June 30, 2024	150	7.71
Issued	—	—
Outstanding September 30, 2024	**150**	$ **7.71**

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Investor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price
Outstanding December 31, 2022	150	$ 7.71
Issued	—	—
Outstanding March 31, 2023	150	7.71
Issued	—	—
Outstanding June 30, 2023	150	7.71
Issued	—	—
Outstanding September 30, 2023	**150**	$ **7.71**

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 6,825 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, 2024, and 2023. For all periods presented, there were no contractor option expense to recognize.

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Employee options expense recognized	1,821	865	3,937	4,497
Total option expense recognized	**$ 1,821**	**$ 865**	**$ 3,937**	**$ 4,497**

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Stock Option Activity

The following is a summary of option activity for the three and nine months ended September 30, 2024 and 2023.

Options	Number of Options (thousands)	Weighted-Average Exercise Price $USD
Outstanding at December 31, 2023	4,798	$ 6.27
Granted	45	7.29
Exercised	(75)	5.81
Forfeited	—	—
Outstanding at March 31, 2024	**4,768**	**5.43**
Granted	707	7.12
Exercised	(147)	2.36
Forfeited	(100)	8.00
Outstanding at June 30, 2024	**5,228**	**6.48**
Granted	558	5.58
Exercised	(55)	2.84
Forfeited	(276)	7.55
Outstanding at September 30, 2024	**5,455**	$ **6.37**

Of the 5,455 options granted and outstanding at September 30, 2024, 4,278 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 stock based on the expected term of the award.

Black-Scholes Model Assumptions	Valuation Assumptions September 30, 2024
Expected dividend	0.00%
Risk free rate	3.79 - 5.15%
Expected volatility	45 - 67%
Expected life	1.5 - 6.0 years

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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, 2024 and 2023. During the three and nine months ended September 30, 2024, there were 48 and 137 RSUs released from restriction, respectively. Vesting of RSUs vary from one to three years.

RSUs Current Year	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2023	218
Awarded	17
Released	(21)
Outstanding at March 31, 2024	214
Awarded	299
Released	(68)
Forfeited	—
Outstanding at June 30, 2024	445
Awarded	—
Released	(48)
Forfeited	(30)
Outstanding at September 30, 2024	**367**

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, 2024 and December 31, 2023 (in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2024	2023	2024	2023	2024	2023	2024	2023
Assets								
Cash and cash equivalents	$ 3,049 (1)	$ 1,340 (1)	$ 37,271	$ 11,929	$ —	$ —	$ 40,320	$ 13,269
Processa common shares	$ 2 (2)	$ 17 (2)	$ —	$ —	$ —	$ —	$ 2	$ 17

(1) The Company held approximately $37,271 in money market accounts as of September 30, 2024. As of December 31, 2023, the Company held approximately $11,929 in money market accounts.

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(2) The Company holds 41 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, Fennec entered into a new exclusive license agreement with 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 royalty on any consideration received from sublicensing of the licensed technology.

On May 18, 2015, Fennec 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 PEDMARK for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments entered 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. Certain milestone payments are due upon FDA approval and achievement of sufficient positive EBITDA over a specified period. PEDMARK received FDA approval in September 2022, however at this time, due to significant uncertainty surrounding timing and magnitude of certain milestones, the Company has only recorded a royalty liability associated with net revenue.

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. The Company now has a licensed product with regulatory approval that is covered by the Orphan Drug Designation, the parties amended the term of the agreement. PEDMARK® is currently protected by methods of use patents that the Company exclusively licensed from OHSU that expired in Europe in 2021 and 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. The Company had accrued approximately $162 in royalty expense to OHSU for the nine-month period ended September 30, 2024. The total amount accrued in royalty expense to OHSU as of September 30, 2024, was $460.

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Litigation

Hope Medical Enterprises, Inc. Inter Partes Review (IPR) 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 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. 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.

The USPTO has now granted six additional U.S. patents that cover the PEDMARK formulation and its use, each of which have been, or are in the process of being, 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), U.S. Patent No. 11,617,793 (issued April 4, 2023), U.S. Patent No. 11,964,018 (issued April 23, 2024)). U.S. Patent No. 11,992,530 (issued May 28, 2024), and U.S. Patent No. 11,998,604 (issued June 4, 2024) Five additional United States patent applications from this family are pending at the USPTO covering various sodium thiosulfate formulations and uses. We plan to vigorously defend our intellectual property rights to PEDMARK if challenged. 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 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.

Under the Food, Drug, and 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, which is September 20, 2029.

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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. CIPLA filed an Answer to the Second Amended Complaint on August 31, 2023.

On April 23, 2024, we were granted US 11,964,018 Patent (the “’018 Patent) covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around May 8, 2024, and has an expiration date of July 2039. On May 28, 2024, we were granted US 11,992,530 Patent (the “’530 Patent”) covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 20, 2024, and has an expiration date of July 2039. On June 4, 2024, we were granted US 11,998,604 Patent (the “’604 Patent”) covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 24, 2024, and has an expiration date of July 2039.

On June 13, 2024, we filed a Motion for Leave to File a Third Amended Complaint to focus the ANDA litigation against CIPLA on the ’018 Patent and the ‘793 Patent only. The non-asserted patents remain listed in the Orange Book. On July 22, 2024, CIPLA filed a response indicating that they do not oppose our Motion for Leave to File a Third Amended Complaint. On July 30, 2024, the court granted us leave to file the Third Amended Complaint. The suit is ongoing.

Further, 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 termination of Mr. Hackman's (Chief Executive Officer) employment 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 $550). In the event of termination of Mr. Andrade’s (Chief Financial Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one-time severance payment equal to nine months of salary which is equivalent to $331. Further, as announced on October 28, 2024, each of Mr. Sayad, Mr. Evans, and Ms. Cioffi’s Executive Employment Agreements generally provide that if their employment is terminated without “Cause” (as defined in the applicable Executive Employment Agreement) and other conditions are satisfied, then such executive officer shall receive as severance an amount equal to their then current base salary for a period of nine (9) months, less standard withholdings for tax and social security purposes.

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 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 month’s advance written notice of termination.

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

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. This lease will terminate on January 31, 2025.

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, 2024
Remaining lease terms (in months)	4
Discount rate	10 %
Maturities of lease liabilities as of December 31, 2023 were as follows (in thousands):	
Year Ending December 31,	
2024	5
2025	2
	7
Less imputed interest	2
Total lease liabilities	$ 5
Current operating lease liabilities	$ 7
Non-current operating lease liabilities	—
Total lease liabilities	$ 7

Employee Benefit Plan

In May 2021, the Company established the Fennec Pharmaceuticals, Inc. 401(k) Plan (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code of 1986. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. As of September 30, 2024, the Company does not offer matching contributions.

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 (see Note 1). On August 19, 2022, the Company closed on 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 on 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 date the Company obtained FDA approval for 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, which was paid by the Company issuing the Investor warrants to purchase 110,996 of the Company's common shares (one half issued at the first closing and the other half issued at the second closing). The warrants are exercisable at a price per share of $8.11 and have a term of five years from the date of the grant.

On December 4, 2023, the Company closed a third tranche under the SPA in the amount of $5,000 and issued the Investor a Note in the same amount that is convertible at a price equal to $7.89 per share, which price was calculated on the same basis as the Second Closing Note.

Also on December 4, 2023, the Company entered into the SPA Amendment, which, among other things, extends the period that the Company may draw the remaining $15,000 under the SPA from December 31, 2023, to December 31, 2024. Subsequent draws are subject to mutual agreement of the Company and the Investor and will be represented by Notes that will also be convertible at a price equal to $7.89 per share.

Cash interest on outstanding principal shall accrue at a rate of prime, plus 4.5% per annum, from the date of funding (13% at September 30, 2024 and 13% as of December 31, 2023). Cash interest is due on the first business day of each calendar quarter ("Interest Date"). 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 $1,600 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 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, 2024, are as follows (in thousands):

Years Ending December 31,	Amount
2024	$ —
2025	—
2026	—
2027	30,000
Payment in kind interest	2,323
Total future payments	32,323
Less: unamortized debt discount	(227)
Total term loan, net of debt discount	$ 32,096

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 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 drawing tranche 1 through 3, the Company recorded a debt discount of $227, 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. License Agreement

License Agreement with Norgine Pharma UK Limited

On March 17, 2024, the Company announced that, through its wholly-owned subsidiary, Fennec Pharmaceuticals, Inc. entered into a License and Supply Agreement (the "Agreement") with Norgine Pharma UK Limited ("Norgine"), pursuant to which Norgine is granted an exclusive license to commercialize the Company's product PEDMARQSI® (known as PEDMARK in the United States) for all human indications in the European Economic Area, Switzerland, the United Kingdom, Australia and New Zealand (collectively, the "Territory"). On July 26, 2024, Norgine and Fennec amended the exclusive licensing agreement. The amended agreement maintains all principal payment terms with the primary addition of Norgine assuming responsibility for packaging and labeling of PEDMARQSI®.

Pursuant to the terms of the Agreement, Fennec shall receive the following payments from Norgine: (i) an upfront payment in the amount of €40,000 or approximately $43,200, which was paid to Fennec on March 15, 2024, (ii) up to €210,000 (or approximately $230,000) upon the achievement of certain regulatory and commercial milestones, and (iii) tiered royalty payments based on net sales of PEDMARQSI® in the Territory, which royalty payment range from mid-teen percent to mid-twenty percent based on the aggregate net sales of PEDMARQSI® in the Territory. The tiered royalty payments are subject to material reduction if an alternative or generic version of PEDMARQSI® becomes available in any respective country or jurisdiction within the Territory.

Subject to customary rights of each party to earlier terminate the Agreement, the term of the Agreement continues for the longer of: (i) March 15, 2034, or (ii) with respect to any particular country in the Territory, (a) the expiration of regulatory market exclusivity for PEDMARQSI® in such country, or (b) the last-to-expire of all patents for PEDMARQSI® in such country. The term of the Agreement shall be automatically renewed for additional three-year periods unless either party

provides the other party written notice of its intent not to renew the Agreement at least one year prior to the applicable termination date of the Agreement.

The Company evaluated the Agreement under ASC 606 and concluded that Norgine represents a customer in the transaction. There were two performance obligations: a license of functional IP and a material right for future supply. The Company will allocate the transaction price, including currently unrecognized variable consideration, to the two performance obligations based on estimated standalone selling price, which was estimated using projected cash flows. The initial transaction price consisted of the non-refundable upfront payment, a portion of which was allocated to and recognized as License Revenue in the first quarter of 2024 as the requirements for revenue recognition under ASC 606 were met. The portion of the transaction price associated with the material right is deferred and reflected as deferred revenue in the condensed consolidated balance sheets. Deferred revenue associated with the material right is recognized as contract liabilities under the supply arrangement are made. The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are dependent on regulatory approvals and actions of third parties, and thus are highly susceptible to factors outside the Company's influence. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue or deferred as part of the material right in the period when the related sales threshold is met. All other milestones will be recognized as revenue or deferred as part of the material right immediately in the period the underlying milestone is achieved. Any consideration related to sales-based royalties will be recognized as revenue or deferred as part of the material right when the related sales occur. For the nine months ended September 30, 2024, the Company did not recognize any milestone or royalty revenue payments from Norgine sales of PEDMARQSI® pursuant to the Agreement.

In conjunction with entering into the Agreement, the Company paid approximately $1,700 in incremental costs, which were capitalized and recorded within other non-current assets. The Company amortizes the asset over the period of expected benefit using a systematic basis that reflects the pattern of transfer to the customer. A portion that represents the license was recognized immediately and is recorded within selling and marketing expense in the condensed consolidated statements of operations. As of September 30, 2024, $948 in incremental cost was capitalized.

9. Subsequent Events

On October 28, 2024, Fennec Pharmaceuticals Inc.'s (the "Company") announced the appointments of Mr. Pierre S. Sayad, PhD, M.S., as Chief Medical Officer ("CMO"), Mr. Terry Evans as Chief Commercial Officer ("CCO"), and Ms. Christiana Cioffi, MBA, as Chief Strategy Officer ("CSO"), all of which became effective on October 28, 2024. There are no arrangements or understandings between each of Mr. Sayad, Mr. Evans, or Ms. Cioffi, and any other person pursuant to which such individual was appointed as CMO, CCO, and CSO, respectively. Neither Mr. Sayad, Mr. Evans, nor Ms. Cioffi have any family relationships with any other executive officer or director of the Company. None of these appointments have been involved in any related person transactions with the Company that would require disclosure under Item 404(a) of Regulation S-K.

In connection with their appointments to CMO, COO, and CSO, respectively, Mr. Sayad, Mr. Evans, and Ms. Cioffi each entered into an Executive Employment Agreement with the Company effective as of October 28, 2024. Each of these Executive Employment Agreements is an "at-will" agreement.

Pursuant to the terms of Mr. Sayad's Executive Employment Agreement, his initial base annualized salary will be at a rate of $450,000, subject to review and increase from time to time by the Company in its sole discretion. He shall be entitled to receive an annual target performance bonus ("Target Bonus") of forty percent (40%) of his base salary per 12-month period (which may be pro-rated for any partial period of less than 12 months), based upon a determination by the Company's Board of Directors ("Board") of the achievement of objectives to be set from time to time by the Board, provided that he must remain employed through the payment date to be eligible to receive the Target Bonus. In addition, the Company will grant Mr. Sayad 150,000 options to purchase common shares of the Company which (i) have an exercise

price per share equal to the "Fair Market Value" (as defined in Company's 2020 Equity Incentive Plan); (ii) have a term of ten years, with one-third of the options vesting one year after the date of grant and the balance thereof vesting monthly thereafter for two years in equal increments, and (iii) are otherwise subject to the terms and conditions set forth in the Company's 2020 Equity Incentive Plan.

Pursuant to the terms of Mr. Evans' Executive Employment Agreement, his initial base annualized salary will be at a rate of $400,000, subject to review and increase from time to time by the Company in its sole discretion. He shall be entitled to receive a Target Bonus of forty percent (40%) of his base salary per 12-month period (which may be pro-rated for any partial period of less than 12 months), based upon a determination by the Board of the achievement of objectives to be set from time to time by the Board, provided that he must remain employed through the payment date to be eligible to receive the Target Bonus. In addition, the Company will grant Mr. Evans 150,000 options to purchase common shares of the Company which (i) have an exercise price per share equal to the "Fair Market Value" (as defined in Company's 2020 Equity Incentive Plan); (ii) have a term of ten years, with one- third of the options vesting one year after the date of grant and the balance thereof vesting monthly thereafter for two years in equal increments, and (iii) are otherwise subject to the terms and conditions set forth in the Company's 2020 Equity Incentive Plan.

Pursuant to the terms of Ms. Cioffi's Executive Employment Agreement, her initial base annualized salary will be at a rate of $375,000, subject to review and increase from time to time by the Company in its sole discretion. She shall be entitled to receive a Target Bonus of forty percent (40%) of her base salary per 12-month period (which may be pro-rated for any partial period of less than 12 months), based upon a determination by the Board of the achievement of objectives to be set from time to time by the Board, provided that she must remain employed through the payment date to be eligible to receive the Target Bonus. In addition, the Company will grant Ms. Cioffi 150,000 options to purchase common shares of the Company which (i) have an exercise price per share equal to the "Fair Market Value" (as defined in Company's 2020 Equity Incentive Plan); (ii) have a term of ten years, with one- third of the options vesting one year after the date of grant and the balance thereof vesting monthly thereafter for two years in equal increments, and (iii) are otherwise subject to the terms and conditions set forth in the Company's 2020 Equity Incentive Plan.

Each of Mr. Sayad, Mr. Evans, and Ms. Cioffi's Executive Employment Agreements generally provide that if their employment is terminated without "Cause" (as defined in the applicable Executive Employment Agreement) and other conditions are satisfied, then such executive officer shall receive as severance an amount equal to their then current base salary for a period of nine (9) months, less standard withholdings for tax and social security purposes.

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, 2023, filed with the SEC on March 29, 2024 (the "Annual Report") and our unaudited interim condensed consolidated financial statements and related notes appearing 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 our plans and strategy for our business, includes forward looking statements, within the meaning of the 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," "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 in the United States and PEDMARQSI® the European brand name for 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®. 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.

On March 17, 2024, we announced that we had entered into an exclusive licensing agreement with Norgine to commercialize PEDMARQSI® in Europe, New Zealand and Australia. The licensing agreement provided us with approximately $43,200 up front and may provide us with up to approximately $230,000 in milestone and royalty payments in the future. Norgine is currently preparing for an EU launch of PEDMARQSI® in the next several months.

In the U.S., we sell our product through an experienced field force 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.

Further, in the United States 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 PEDMARK 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 six 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. Further, additional issued patents included US 11,964,018 Patent (the "'US 018' Patent) and US 11,992,530 Patent (the "US '530 Patent") and US 11,998,604 Patent (the "'604 Patent") covering methods of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '728, US '984 US '793, US '018, US'530 and US'604 patents 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.

Results of Operations

Three months ended September 30, 2024 versus three months ended September 30, 2023:

In thousands of U.S. Dollars	Three Months Ended September 30, 2024	%	Three Months Ended September 30, 2023	%	Change
Product sales, net	$ 6,974		$ 6,515		$ 459
Operating expenses:					
Cost of product sales	1,357	11 %	331	4 %	1,026
Research and development	97	1 %	12	0 %	85
Selling and marketing	4,601	38 %	3,384	45 %	1,217
General and administration	6,121	50 %	3,805	51 %	2,316
Total operating expense	12,176	100 %	7,532	100 %	4,644
Loss from operations	(5,202)		(1,017)		(4,185)
Unrealized loss on securities	(3)		(13)		10
Amortization expense	(21)		(72)		51
Interest expense	(1,025)		(856)		(169)
Unrealized foreign exchange (loss)/gain	—		(11)		11
Interest income	516		102		414
Net loss	$ (5,735)		$ (1,867)		$ (3,868)

- We reported net product sales for the three-month period ended September 30, 2024 of $6,974 and gross profit of $5,617 compared to net product sales of $6,515 and gross profit of $6,184 in the comparable period in 2023.

- Research and development expenses increased by $85 for the three months ended September 30, 2024, compared to the same period in 2023. Our research and development activities for this period consisted of costs associated with investigator initiated clinical trials. During the same period in 2023 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 $4,601 for the three months ended September 30, 2024 compared to $3,384 for the comparable three month period in 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. The increase is largely related to increased payroll and additional marketing expenses in the comparable period as we focused on expanding our outreach to community oncology centers and the adolescent and young adult (AYA) population.

- General and administrative expenses increased by $2,316 compared to the same period in 2023, as a result of an increase in select expenses such as salaries, equity renumeration and intellectual property litigation expenses compared to the same period in 2023.

- Interest expense increased $169 compared to the same period in 2023. This increase is associated with higher debt levels as compared with the same period in 2023.

- Additionally, we hold shares of Processa Pharmaceuticals, Inc. (“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 us decreased for the three month period ended September 30, 2024, as compared with the same period in 2023. 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.

- 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 decreased by $51 for the three months ended September 30, 2023, compared to the same period in 2023. Interest income increased by $414 for the three months ended September 30, 2024, compared to the same period in 2023. This increase in interest income was primarily driven by a higher cash balance and higher interest rates for the three months ended September 30, 2024, compared to the same period in 2023.

Nine months ended September 30, 2024, versus nine months ended September 30, 2023:

In thousands of U.S. Dollars	Nine Months Ended September 30, 2024	%	Nine Months Ended September 30, 2023	%	Change
Product sales, net	$ 21,655		$ 11,517		$ 10,138
Licensing revenue	17,958		—		17,958
Total Net revenue	39,613		11,517		28,096
Operating expenses:					
Cost of product sales	2,515	7 %	574	3 %	1,941
Research and development	257	1 %	24	0 %	233
Selling and marketing	14,482	40 %	8,255	37 %	6,227
General and administration	18,857	52 %	13,617	61 %	5,240
Total operating expense	36,111	100 %	22,470	100 %	13,641
Loss from operations	3,502		(10,953)		14,455
Unrealized loss on securities	(14)		(43)		29
Amortization expense	(64)		(217)		153
Interest expense	(3,103)		(2,479)		(624)
Unrealized foreign exchange (loss)/gain	(55)		3		(58)
Interest income	1,283		326		957
Net loss	$ 1,549		$ (13,363)		$ 14,912

- We recorded net product sales of $21,655 and $17,958 in licensing revenue related to the Norgine transaction for the nine-month period ended September 30, 2024, compared to $11,517 in net product sales and no licensing revenue for the same period in 2023.

- Selling and marketing expenses include distribution costs, logistics, shipping and insurance, advertising, wages commissions and out-of-pocket expenses. We recorded $14,482 in selling and marketing expenses for the nine-month period ended September 30, 2024, compared to $8,255 for the same period in 2023. The increase is largely related to increased payroll and additional marketing expenses in the comparable period as we focused on expanding our outreach to community oncology centers and the adolescent and young adult (AYA) population.

- There was a $5,240 increase in general and administrative expenses for the nine-months ended September 30, 2024, compared to same period in 2023. There was an increase in consulting and professional costs compared to same period in 2023 which is largely attributable to increased European pre-commercialization related expenses and expenses associated with the Norgine transaction and intellectual property expenses related to ongoing litigation.

- The value of the Processa shares held by us declined by $14 for nine-months ended September 30, 2024. The shares declined in value by $43 during same period in 2023. We acquired the Processa shares on October 30, 2020. The Processa shares are marked to market at each balance sheet date with the resulting change in value being booked as an unrealized gain or loss.

- Amortization expense decreased by $153 for nine-months ended September 30, 2024, over the same period in 2023.

- Interest expenses increased by $624 for the nine-month ended September 30, 2024 compared to the same period in 2023. The increase was driven mainly by higher average debt balances and higher interest rates on long-term debt.

- Interest income increased by $957 for the nine-months ended September 30, 2024, as compared to the same period in 2023, due to higher cash balances and higher rates on money market accounts for the comparable periods.

Liquidity and Capital Resources

Selected Asset and Liability Data (thousands):	As of September 30, 2024	As of December 31, 2023
Cash and equivalents	$ 40,320	$ 13,269
Other current assets	17,645	13,589
Current liabilities	7,435	7,553
Working capital [(1)]	50,530	19,305
[(1)] [Current assets – current liabilities]		
Selected Equity:		
Common stock and additional paid in capital	211,282	206,380
Accumulated deficit	(217,696)	(219,245)
Stockholders' deficit	(5,171)	(11,622)

Cash and cash equivalents were $40,320 as of September 30, 2024, and $13,269 at December 31, 2023. The increase in cash and cash equivalents between September 30, 2024 and December 31, 2023 is the result of cash outlays for operating expenses related to the promotion of our product, small amounts of research and development and general and administrative expenses, which were offset by cash inflows of $43,200 from Norgine licensing deal, cash collections on product sales of $8,923 and cash inflows of $1,131 from various option exercises. There was an increase of $4,056 other current assets between September 30, 2024, and December 31, 2023, and a decrease in current liabilities of $118. The overall result was an increase in working capital of $31,225.

The following table illustrates a summary of cash flows data for the nine-month periods of September 30, 2024 and 2023:

Selected Cash Flow Data (dollars and shares in thousands)	Nine Months Ended September 30, 2024	2023
Net cash provided by / (used in) operating activities	$ 28,454	$ (12,283)
Net cash provided by investing activities	—	—
Net cash (used in) / provided by financing activities	(1,403)	908
Net cash flow	$ 27,051	$ (11,375)

Net cash provided by operating activities for the nine-month period ended September 30, 2024 and 2023, primarily reflected a net income of $1,549 and a net loss of $13,363 million respectively. The nine-month income was adjusted for the add back of non-cash items consisting of $5,893 and $5,434, respectively, in stock-based compensation expense, amortization of debt access fee of $774 and $166, respectively, and addition of PIK interest of $1,104 and 677, respectively, for the nine months ended September 30, 2024, and 2023. For the nine months ended September 30, 2024 there was an increase in other current assets of $3,455 and $3,636 during the same period in 2023. For the nine months ended September 30, 2024, there was a net increase in current liabilities of $24,457 and a net decrease of $41 during the same period in 2023. Nine-month cash flows provided by operating activities were $28,454 million and net cash flows used in operating activities were $12,283, respectively, for the periods ended September 30, 2024 and 2023. Net cash flows used in financing activities for the nine months ended September 30, 2024, were $1,403 and net cash provided were $908, respectively. Net cash flows from the nine-month period ended September 30, 2024, and 2023, were positive $27,051, and negative $11,375, 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, 2024 and December 31, 2023 was as follows (in thousands):

Outstanding Share Type	September 30, 2024	December 31, 2023	Change
Common shares	27,422	27,027	395
Warrants	150	150	—
Stock options	5,455	5,032	423
Total	33,027	32,209	818

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, 2024, we had approximately $3,049 in our cash accounts and $37,271 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, lease agreements, and severance amounts described in notes to our condensed consolidated financial statements contained elsewhere in this Quarterly 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, 2024.

Revenue Recognition

Under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, we recognizes revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we determine we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform 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) we satisfy our performance obligation(s). As part of the accounting for these arrangements, we must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Stock-based Compensation

The calculation of the fair values of our stock-based compensation plans requires estimates that require management's judgments. Under ASC 718, the fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model. The valuation models require assumptions and estimates to determine expected volatility, expected life, expected dividends and expected risk-free interest rates. The expected volatility was determined using historical volatility of our stock based on the contractual life of the award. The risk-free interest rate assumption was based on the yield on zero-coupon U.S. Treasury strips at the award grant date. We also used historical data to estimate forfeiture experience. In valuing options granted in the fiscal years ended September 30, 2024, we used the following weighted average assumptions:

Black-Scholes Model Assumptions	Valuation Assumptions September 30, 2024
Expected dividend	0.00%
Risk free rate	3.79 - 5.15%
Expected volatility	45 - 67%
Expected life	1.5 - 6.0 years

Common shares and warrants

Common shares are recorded as the net proceeds received on issuance after deducting all share issuance costs and the relative fair value of investor warrants. Warrants are recorded at relative fair value and are deducted from the proceeds of common shares and recorded on the consolidated statements of shareholders' equity (deficit) as additional paid-in capital.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of September 30, 2024. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports our files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including the our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, our 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. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints that require our management to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2024, our disclosure controls and procedures were not effective because of a material weakness in our internal control over financial reporting related to fees and allowances paid to distributors for distinct services.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management evaluated the effectiveness of its internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that evaluation, our management has concluded that, as of September 30, 2024, our internal controls over financial reporting were not effective because of the existence of a material weakness in internal control over financial reporting related to fees and allowances paid to distributors for distinct services.

A material weakness is defined as a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

With respect to the fees and allowances paid to distributors for distinct services, the execution of the controls over the application of accounting literature did not operate effectively with respect to:

- Measurement and classification of fees paid to customers for distinct services under ASC 606 Revenue from Contracts with Customers.
- Measurement of services received and expensed in a reporting period, measurement of services that pertain to future periods, and the periods of attribution for those future services.

We are evaluating the material weaknesses and developing a plan of remediation to strengthen the effectiveness of the design and operation of its internal control environment. The remediation plan will include the following actions:

- Enhance the formality of its review procedures with respect to accounting for new contracts with customers.

- Strengthen the review process to improve the operation of accounting and review controls with respect to complex and non-recurring transactions, as well as those transactions that require significant estimates and judgments.

- Engaging additional service providers or hiring additional full-time employees may be necessary and advisable to address these weaknesses.

The actions that we are taking are subject to ongoing senior management review as well as Audit Committee oversight. We are committed to maintaining a strong internal control environment and believes that these remediation efforts will represent significant improvements in our controls. We have started to implement these steps including hiring additional full-time employee to assist with technical accounting and financial reporting; however, some of these steps will take time to be fully integrated and confirmed to be effective and sustainable. Additional controls may also be required over time. Until the remediation steps set forth above are fully implemented and tested, the material weakness described above will continue to exist.

(b) Changes in Internal Control over Financial Reporting.

We are in the process of implementing changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) but do not believe any of these changes, as of the period covered by this Quarterly Report on Form 10-Q have 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 elsewhere in 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. Please see below for additional risk factors:

We have entered into, and may in the future enter into, strategic transactions for the research, development and commercialization of PEDMARK. If any of these transactions are not successful, then we may not be able to capitalize on the market potential of such product candidates. Further, we may not be able to enter into future transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize our potential future product candidates and former lead product candidate, impact our cash position, increase our expense, and present significant distractions to our management.

We have entered into, and may enter into in the future, strategic transactions, such as out-licensing of product candidates or technologies. For example, in March 2024, we entered into a collaboration and license agreement with Norgine. Our ability to generate revenue from any of our strategic transactions will depend on our partners' abilities to successfully perform the functions assigned to them in these transactions. We cannot predict the success of any of our strategic transactions.

We also intend to evaluate and, if strategically attractive, seek to enter into additional collaborations in the future, including with biotechnology or biopharmaceutical companies or hospitals. The competition for partners is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our discovery platform.

Any existing or potential future collaboration or other strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of such acquisitions or collaborations. In addition, any new collaboration that we enter into may be on terms that are not optimal for us.

Our existing and future strategic transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, potential future product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs;
- higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses;
- collaborators have significant discretion in determining the efforts and resources they apply to these collaborations, and may not pursue development of any product candidates we may develop or may elect not to continue development programs based on preclinical study results, changes in the collaborator's strategic focus or other factors that may be beyond our control;
- collaborators could independently develop, or develop with third parties, products that may compete directly or indirectly with our potential future product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- potential future product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our potential future product candidates;
- difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business;
- disputes may arise between a collaborator and us, including with respect to the ownership of any intellectual property developed pursuant to our collaborations, that cause the delay or termination of the research, development or commercialization of a potential future product candidate, or that result in costly litigation or arbitration that diverts management's attention and resources;
- impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and
- the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above, any collaborations that we are currently engaged in or transactions we may complete in the future may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our potential future product candidates and have a negative impact on the competitiveness of any potential future product candidate that reaches market.

In addition, to the extent that any of our existing or future partners were to terminate a collaboration agreement, we may be forced to independently develop our future product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandon potential future product candidates altogether, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects.

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.

Rostislav Raykov, a current member of our Board of Directors, adopted a trading arrangement on September 23, 2024, which is intended to satisfy the Rule 10b5-1 affirmative defense. This trading arrangement covers the disposition of up to 120,000 shares of the Company's common shares, and will terminate on December 31, 2025, unless earlier terminated in accordance with its terms. No additional directors or officers informed us of the adoption, modification or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

On November 8, 2024, we issued a press release announcing our financial results for the quarter ended September 30, 2024. 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, 2024 (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 8, 2024

By: */s/ Jeff Hackman*
Jeff Hackman
Chief Executive Officer
(principal executive officer)

Date: November 8, 2024

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

Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Jeffrey Hackman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024 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 8, 2024

By: /s/ Jeffrey Hackman
Jeffrey Hackman
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, 2024, 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 8, 2024

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, 2024 (the "Report"), each of the undersigned, Jeffrey Hackman, 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 8, 2024

By: /s/ Jeffrey Hackman
Jeffrey Hackman
Chief Executive Officer

Date: November 8, 2024

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

FENNEC PHARMACEUTICALS REPORTS THIRD QUARTER 2024 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ Achieved Third Quarter 2024 Net Product Sales of $7.0 Million ~

~ Increasing Momentum and Successful Reimbursement in the Adolescent and Young Adult (AYA) Segment Following Strategic Investments to Drive Awareness of Ototoxicity & Adoption of PEDMARKÒ ~

~ Strengthened Executive Leadership Team with Chief Medical Officer, Chief Commercial Officer & Chief Strategy Officer Appointments ~

~ Company Has Approximately $40 Million in Cash, Cash Equivalents, and Investment Securities Expected to Fund Operations Into at Least 2026 ~

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

Research Triangle Park, NC, November 7, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the third quarter ended September 30, 2024, and provided a business update.

"I am pleased with the progress that we have made since recently joining Fennec in August as CEO. We are making significant headway that will position us for near-term and sustainable growth, including market expansion to the Adolescent and Young Adult (AYA) community with payor reimbursement, and adoption within prominent academic centers," said Jeff Hackman, chief executive officer of Fennec Pharmaceuticals. "Our strategic and focused investments in educational initiatives reflect the strength of the foundation we are building upon with PEDMARKÒ. Together with the recent executive leadership team appointments combined with Fennec's talented employee base, I believe that we are well positioned to execute, accelerate growth and unlock value across all key market segments."

Recent Developments and Highlights:

- **Appointed Pierre S. Sayad, PhD, M.S., as chief medical officer, Terry Evans as chief commercial officer and Christiana Cioffi, MBA, as chief strategy officer.** Seasoned biopharmaceutical industry executives with proven clinical, commercial, sales, operational, and oncology market expertise will significantly accelerate our ability to build upon and seamlessly execute our integrated commercial strategy for PEDMARKÒ and create shareholder value.

- **Surpassed greater than 90% reimbursement for PEDMARKÒ in the AYA population in Q3.** Insights from a market and situational analysis to better understand patient incidence and

addressable patient populations identified significant near-and long-term opportunities across the Pediatric and AYA market segments. The opportunity for the AYA segment is significant with at least 10,000 patients treated annually with cisplatin, including primary tumors such as germ cell tumors and thyroid tumors. The incidence of ototoxicity induced by cisplatin has been estimated to be 36% of adult patients with cancer and 40%-60% of pediatric cancer patients.[1]

- **PEDMARQSI® commercial launch in Europe**: Following the exclusive licensing agreement announcement executed in March with Norgine, PEDMARQSI is expected to be available in select markets in Europe in the coming months, which will generate additional revenue for Fennec in 2025 and beyond.

- **Investigator-initiated clinical trial (STS-J01) in Japan evaluating PEDMARK® fully enrolled in October 2024:** The clinical trial of STS-J01 evaluates the efficacy and safety of PEDMARK in reducing ototoxcity induced by cisplatin in children and AYAs with localized solid tumors. The primary endpoint of the trial is to assess the frequency of hearing impairment at the end of treatment. Results of the trial are expected in 2025 with the potential evaluation for registration of PEDMARK in Japan thereafter.

- **Participation in Key Scientific Meetings:** During the third quarter, Fennec actively participated in key regional and national scientific meetings, including the National Community Oncology Dispensing Association (NCODA) International Fall Summit, the Testicular Cancer Awareness Foundation's annual Conference and the Association of Pediatric Hematology/Oncology Nurses (APHON) annual meeting.

Financial Results for the Third Quarter 2024

- **Net Product Sales –** The Company recorded net product sales of $7.0 million for the three-month period ended September 30, 2024, compared to $6.5 million in net product sales for the same period in 2023.

- **Cash Position –** Cash and cash equivalents were $40.3 million on September 30, 2024. Cash decreased by $2.7 million over the previous quarter. The decrease in cash is the result of cash inflows from net sales offset by cash outlays for operating expenses related to the promotion of our product, selling and marketing expenses and general and administrative expenses. We anticipate that our cash, cash equivalents and investment securities as of September 30, 2024 will be sufficient to fund our planned operations into at least 2026.

- **Selling and Marketing Expenses** –The Company recorded $4.6 million in selling and marketing expenses for the period ended September 30, 2024, compared to $3.4 million for the same period in 2023. The increase is largely related to additional selling and marketing expenses as the Company expanded its focus in the AYA and community oncology population during 2024.

- **General and Administrative (G&A) Expenses** – G&A expenses were $6.1 million compared to $3.8 million in the same period in 2023 and $6.9 million in the second quarter of 2024. The

increase includes additional expenses related to non-cash equity compensation, one-time severance related to our previous CEO and ongoing IP litigation expenses.

- **Net Earnings –** Net loss for the quarter ended September 30, 2024 was $5.7 million (basic and diluted loss of $0.21 per share) compared to a net loss of $1.9 million (basic and diluted loss of $0.07 per share) for the same period in 2023.

Q3 2024 Conference Call Information

Date: Thursday, November 7, 2024
Time: 8:30 a.m. ET
Link: https://edge.media-server.com/mmc/p/e6my278s
To access the conference call, dial 888-596-4144 or 646-968-2525 internationally and referencing the conference access ID: 6896851. To access the live webcast link, log onto www.fennecpharma.com and proceed to the News & Events/Event Calendar page under the Investors & Media heading. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to listen to the webcast. A webcast replay of the conference call will also be archived on www.fennecpharma.com for thirty days.

Financial Update

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements, which were prepared in accordance with U.S. generally accepted accounting principles. The complete unaudited condensed consolidated financial statements for the period ended September 30, 2024 and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

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

	Three Months Ended	
	September 30, 2024	September 30, 2023
Revenue		
PEDMARK product sales, net	$ 6,974	$ 6,515
Operating expenses:		
Cost of products sold	1,357	331
Research and development	97	12
Selling and marketing	4,601	3,384
General and administrative	6,121	3,805
Total operating expenses	(12,176)	7,532
Loss from operations	(5,202)	(1,017)
Other (expense)/income		
Unrealized foreign exchange loss	—	(11)
Amortization expense	(21)	(72)
Unrealized loss on securities	(3)	(13)
Interest income	516	102
Interest expense	(1,025)	(856)
Total other (expense)/income	(533)	(850)
Net loss	$ (5,735)	$ (1,867)
Basic net loss per common share	$ (0.21)	$ (0.07)
Diluted net loss per common share	$ (0.21)	$ (0.07)
Weighted-average number of common shares outstanding basic	27,371	26,596
Weighted-average number of common shares outstanding diluted	27,371	26,596

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

	Unaudited September 30, 2024	Audited December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 40,320	$ 13,269
Accounts receivable, net	12,908	8,814
Prepaid expenses	3,066	2,575
Inventory	1,125	2,156
Other current assets	546	44
Total current assets	57,965	26,858
Non-current assets		
Deferred issuance cost, net amortization	956	6
Total non-current assets	956	6
Total assets	$ 58,921	$ 26,864
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 3,867	$ 3,778
Accrued liabilities	3,313	3,754
Deferred revenue-current	248	21
Operating lease liability-current	7	—
Total current liabilities	7,435	7,553
Non-current liabilities		
Term loan	30,000	30,000
PIK interest	2,323	1,219
Debt discount	(227)	(288)
Contract liability	24,561	2
Total non-current liabilities	56,657	30,933
Total liabilities	64,092	38,486
Shareholders'(deficit) equity:		
Common stock, no par value; unlimited shares authorized; 27,422 shares issued and outstanding (2023 -27,027)	145,438	144,307
Additional paid-in capital	65,844	62,073
Accumulated deficit	(217,696)	(219,245)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(5,171)	(11,622)
Total liabilities and shareholders' (deficit) equity	$ 58,921	$ 26,864

Working Capital

Working capital	Fiscal Period Ended	
Selected Asset and Liability Data:	**September 30, 2024**	**December 31, 2023**
(U.S. Dollars in thousands)		
Cash and equivalents	$ 40,320	$ 13,269
Other current assets	17,645	13,589
Current liabilities	7,435	7,553
Working capital	$ 50,530	$ 19,305
Selected Equity:		
Common stock and additional paid in capital	211,282	206,380
Accumulated deficit	(217,696)	(219,245)
Shareholders' (deficit) equity	(5,171)	(11,622)

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.[ii]

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.[iii] 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.[iv]

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

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

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

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

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

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

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

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

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

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

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

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

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

About Fennec Pharmaceuticals
Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and U.K. approval in October 2023 under the brand name PEDMARQSI©. PEDMARK has received Orphan Drug Exclusivity in the U.S. and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. For more information, please visit www.fennecpharma.com.

Forward Looking Statements
Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2023. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

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

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[ii] Rybak L. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. Current Opinion in Otolaryngology & Head and Neck Surgery. 2007, Vol. 15: 364-369.

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[iv] 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.