

**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, 2025  
OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_ to \_\_\_  
Commission File Number: 001-32295

**FENNEC PHARMACEUTICALS INC.**  
(Exact Name of Registrant as Specified in Its Charter)

British Columbia, Canada  
(State or Other Jurisdiction of  
Incorporation or Organization)

20-0442384  
(I.R.S. Employer  
Identification No.)

PO Box 13628, 68 TW Alexander Drive  
Research Triangle Park, North Carolina  
(Address of Principal Executive Offices)

27709  
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

Large Accelerated Filer   
Non-Accelerated Filer

Accelerated Filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 10, 2025, there were 28,116,829 of the registrant's common shares outstanding.

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

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 21,947	\$ 26,634
Accounts receivable, net	19,343	12,884
Prepaid expenses	1,399	3,080
Inventory, net	2,477	1,060
Other current assets	898	466
<b>Total current assets</b>	<u>46,064</u>	<u>44,124</u>
<b>Non-current assets</b>		
Non-current accounts receivable, net	2,454	—
Other non-current assets, net of amortization	743	822
<b>Total non-current assets</b>	<u>3,197</u>	<u>822</u>
<b>Total assets</b>	<u>\$ 49,261</u>	<u>\$ 44,946</u>
<b>Liabilities and stockholders' deficit</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 5,866	\$ 3,241
Accrued liabilities	3,701	3,428
Contract liability - current	248	248
Operating lease liability - current	—	2
<b>Total current liabilities</b>	<u>9,815</u>	<u>6,919</u>
<b>Long-term liabilities</b>		
Term loan	18,206	18,206
PIK interest	1,271	1,271
Debt discount	(100)	(139)
Contract liability - long-term	24,561	24,561
<b>Total long-term liabilities</b>	<u>43,938</u>	<u>43,899</u>
<b>Total liabilities</b>	<u>53,753</u>	<u>50,818</u>
<b>Commitments and contingencies (Note 6)</b>		
<b>Stockholders' deficit:</b>		
Common stock, no par value; unlimited shares authorized; 28,062 shares issued and outstanding (2024 -27,527)	147,652	145,608
Additional paid-in capital	71,249	66,958
Accumulated deficit	(224,636)	(219,681)
Accumulated other comprehensive income	1,243	1,243
<b>Total stockholders' deficit</b>	<u>(4,492)</u>	<u>(5,872)</u>
<b>Total liabilities and stockholders' deficit</b>	<u>\$ 49,261</u>	<u>\$ 44,946</u>

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, 2025	September 30, 2024	September 30, 2025	September 30, 2024
<b>Revenue</b>				
PEDMARK product sales, net	\$ 12,462	\$ 6,974	\$ 30,865	\$ 21,655
Licensing revenue	—	—	—	17,958
<b>Total revenue</b>	<u>12,462</u>	<u>6,974</u>	<u>30,865</u>	<u>39,613</u>
<b>Operating expenses:</b>				
Cost of product sales	660	1,357	2,000	2,515
Research and development	29	97	230	257
Selling and marketing	5,210	4,601	12,510	14,482
General and administrative	6,752	6,121	19,853	18,857
<b>Total operating expenses</b>	<u>(12,651)</u>	<u>(12,176)</u>	<u>(34,593)</u>	<u>(36,111)</u>
<b>(Loss)/income from operations</b>	<u>(189)</u>	<u>(5,202)</u>	<u>(3,728)</u>	<u>3,502</u>
<b>Other (expense)/income</b>				
Unrealized foreign exchange (loss)/gain	(3)	—	27	(55)
Amortization expense	(12)	(21)	(38)	(64)
Unrealized loss on securities	—	(3)	(2)	(14)
Interest income	152	516	559	1,283
Interest expense	(586)	(1,025)	(1,772)	(3,103)
Total other expense	(449)	(533)	(1,226)	(1,953)
<b>Net (loss)/income</b>	<u>\$ (638)</u>	<u>\$ (5,735)</u>	<u>\$ (4,954)</u>	<u>\$ 1,549</u>
<b>Basic net (loss)/income per common share</b>	<u>\$ (0.02)</u>	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>	<u>\$ 0.06</u>
<b>Diluted net (loss)/income per common share</b>	<u>\$ (0.02)</u>	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>	<u>\$ 0.06</u>
<b>Weighted-average number of common shares outstanding basic</b>	<u>27,889</u>	<u>27,371</u>	<u>27,711</u>	<u>27,371</u>
<b>Weighted-average number of common shares outstanding diluted</b>	<u>27,889</u>	<u>27,371</u>	<u>27,711</u>	<u>28,015</u>

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, 2025, and 2024**  
**(U.S. dollars and shares in thousands)**  
**(Unaudited)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2024</b>	27,527	\$ 145,608	\$ 66,958	\$ (219,681)	\$ 1,243	\$ (5,872)
Stock-based compensation	—	—	798	—	—	798
Stock option exercise	55	371	—	—	—	371
Restricted stock release	12	—	(12)	—	—	(12)
Net loss	—	—	—	(1,165)	—	(1,165)
<b>Balance at March 31, 2025</b>	<b>27,594</b>	<b>145,979</b>	<b>67,744</b>	<b>(220,846)</b>	<b>1,243</b>	<b>(5,880)</b>
Stock-based compensation	—	—	1,494	—	—	1,494
Stock option exercise	52	186	—	—	—	186
Restricted stock release	87	—	(111)	—	—	(111)
Net loss	—	—	—	(3,152)	—	(3,152)
<b>Balance at June 30, 2025</b>	<b>27,733</b>	<b>146,165</b>	<b>69,127</b>	<b>(223,998)</b>	<b>1,243</b>	<b>(7,463)</b>
Stock-based compensation	—	—	2,219	—	—	2,219
Warrant exercise	9	59	(59)	—	—	—
Stock option exercise	257	1,428	—	—	—	1,428
Restricted stock release	63	—	(38)	—	—	(38)
Net loss	—	—	—	(638)	—	(638)
<b>Balance at September 30, 2025</b>	<b>28,062</b>	<b>\$ 147,652</b>	<b>\$ 71,249</b>	<b>\$ (224,636)</b>	<b>\$ 1,243</b>	<b>\$ (4,492)</b>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2023</b>	27,027	\$ 144,307	\$ 62,073	\$ (219,245)	\$ 1,243	\$ (11,622)
Stock-based compensation	—	—	1,191	—	—	1,191
Stock option exercise	75	627	—	—	—	627
Restricted stock release	3	—	(19)	—	—	(19)
Net income	—	—	—	12,837	—	12,837
<b>Balance at March 31, 2024</b>	<b>27,105</b>	<b>144,934</b>	<b>63,245</b>	<b>(206,408)</b>	<b>1,243</b>	<b>3,014</b>
Stock-based compensation	—	—	925	—	—	925
Stock option exercise	147	347	—	—	—	347
Restricted stock release	77	—	(90)	—	—	(90)
Net loss	—	—	—	(5,553)	—	(5,553)
<b>Balance at June 30, 2024</b>	<b>27,329</b>	<b>145,281</b>	<b>64,080</b>	<b>(211,961)</b>	<b>1,243</b>	<b>(1,357)</b>
Stock-based compensation	—	—	1,821	—	—	1,821
Stock option exercise	55	157	—	—	—	157
Restricted stock release	38	—	(57)	—	—	(57)
Net loss	—	—	—	(5,735)	—	(5,735)
<b>Balance at September 30, 2024</b>	<b>27,422</b>	<b>\$ 145,438</b>	<b>\$ 65,844</b>	<b>\$ (217,696)</b>	<b>\$ 1,243</b>	<b>\$ (5,171)</b>

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)**

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	<b>September 30,</b>
	<b>2025</b>	<b>2024</b>
<b>Cash flows (used in) provided by:</b>		
<b>Operating activities:</b>		
Net loss	\$ (4,954)	\$ 1,549
Adjustments to reconcile net loss to net cash used in operating activities:		
Inventory reserve	(517)	517
Allowance for credit losses	67	3,604
Amortization of debt discount	38	64
Loss on securities	2	14
Amortization of Norgine asset	77	774
PIK interest	—	1,104
Stock-based compensation - employees	4,511	3,937
Changes in operating assets and liabilities:		
Accounts receivable	(8,982)	(7,698)
Prepaid expenses	1,681	(491)
Inventory	(1,417)	514
Other assets	85	109
Accounts payable	2,625	89
Accrued liabilities	273	(441)
Contract liability - Norgine	—	24,809
Net cash (used in)/provided by operating activities	(6,511)	28,454
<b>Financing activities:</b>		
Issuance of shares, options exercise	1,985	504
Cash paid for taxes on restricted share release	(161)	(167)
Deferred issuance costs	—	(1,740)
Net cash provided by/(used in) financing activities	1,824	(1,403)
(Decrease)/increase in cash and cash equivalents	(4,687)	27,051
Cash and cash equivalents - Beginning of period	26,634	13,269
Cash and cash equivalents - End of period	\$ 21,947	\$ 40,320
<b>Non-cash investing and financing activities:</b>		
Capitalized lease asset	\$ —	\$ 21

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 Liquidity**

Fennec Pharmaceuticals Inc., a corporation existing under the laws of British Columbia (“Fennec,” “the Company,” “we,” “us,” or “our”). Fennec, together with its wholly owned subsidiaries Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian corporation, and Fennec Pharmaceuticals (EU) Limited, an Ireland company (“Fennec Limited”), collectively referred to herein as the “Company,” is a biopharmaceutical company with one U.S. Federal Drug Administration (“FDA”), European Medicines Agency (“EMA”) and U.K. approved product 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. With the exception of Fennec Pharmaceuticals, Inc., 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, 2025, the Company experienced a net loss from operations of \$(189) and \$(3,728), respectively. On September 30, 2025, it had an accumulated deficit of \$(224,636), and had experienced negative cash flows from operating activities in the amount of \$(6,511) for the nine-month period ended September 30, 2025.

On August 1, 2022, the Company entered into a Securities Purchase Agreement (the “SPA”) with Petrichor Opportunities Fund I LP (the “Petrichor”) 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”). The notes are due in August 2027. 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. In connection with the first closing, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of \$5,000.

On September 23, 2022, the Company closed 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®.

A commitment fee of 2.0% of the Notes was payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 Fennec common shares (“First Closing Warrant”) and half was payable in cash or warrants of 55,498 Fennec common shares (“Second Closing Warrant”), at our election, on 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. The Company elected to have all the commitment fee of the Notes payable in warrants.

On December 4, 2023, the Company closed a third tranche under the SPA in the amount of \$5,000 (the “Third 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®.

Also on December 4, 2023, the Company entered into a First Amendment to the Securities Purchase Agreement (the “SPA Amendment”) with Petrichor, which, among other things, extend the period that the Company could draw the remaining \$15,000 under the SPA from December 31, 2023, to December 31, 2024. The ability to draw the remaining \$15,000 under the SPA expired on December 31, 2024.

On December 18, 2024, the Company entered into a Waiver and Redemption Agreement (the “Redemption Agreement”) with Petrichor, pursuant to which the Company repurchased and redeemed Notes in an aggregate principal amount of \$13,000 (consisting of approximately \$11,800 of original principal balance and approximately \$1,271 in Payment-in-kind (“PIK”) interest) (collectively, the “Note Redemptions”).

As a result of the Note Redemptions, the First and Third Closing Notes were repurchased and redeemed in full, and, as of September 30, 2025, there remains outstanding Second Closing Notes in the aggregate principal amount (inclusive of PIK interest) of approximately \$19,477.

In March of 2024, the Company announced that it had secured an exclusive licensing agreement with Norgine Pharma UK Limited (“Norgine”) to commercialize PEDMARQSI<sup>®</sup>, which is the branded name for PEDMARK<sup>®</sup>, in Europe, Australia and New Zealand. The deal provided the Company with approximately \$43,000 up front, with the potential of approximately another \$230,000 in future royalties and milestone payments.

The Company believes current funds, which include funds from the upfront payment from Norgine and current operating activities, provide sufficient funding for the Company to carry out its planned activities, including the continuation of commercialization efforts of PEDMARK<sup>®</sup>, for at least the next twelve months.

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, 2024. 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, 2024. 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 and employees support only one operating segment which is the production and commercialization of PEDMARK<sup>®</sup>.

### **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.

In May and August 2025, the Board of Directors approved performance-based units ("PSUs") grants whereby vesting depends on certain revenue performance milestones through December 31, 2025. The Company estimates the likelihood of achievement of performance milestones for all PSU awards at the end of each reporting period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. As of September 30, 2025, the Company deems the achievement of the performance milestones to be probable.

### **Inventory**

Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, 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.

### **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<sup>®</sup> 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<sup>®</sup> became commercially available on October 17, 2022. PEDMARK<sup>®</sup> is the Company's first commercial product. Amongst the Company's customers are distributors which subsequently resell the Company's products to health care providers and patients. In addition to distribution agreements, 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.

#### **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<sup>®</sup> and PEDMARQSI<sup>®</sup> (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:* The customers receive a discount for prompt payment which may range from 0.5% to 2.0%. 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<sup>®</sup> 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<sup>®</sup>. 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.

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The following table summarizes net product revenues for PEDMARK<sup>®</sup> earned during the three and nine months ended September 30, 2025, and 2024, respectively:

In thousands	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2025	2024	2025	2024
Product revenues:				
Gross product revenues	\$ 13,668	\$ 7,986	\$ 35,421	\$ 27,008
Discounts and allowances	(1,206)	(1,012)	(4,556)	(5,353)
Net product revenues	<u>\$ 12,462</u>	<u>\$ 6,974</u>	<u>\$ 30,865</u>	<u>\$ 21,655</u>

For the three and nine months ended September 30, 2025, the Company had two and three distributors that each represented more than 10% of net sales, respectively.

The activities and ending allowance balances for each significant category of discounts and allowances for PEDMARK<sup>®</sup> (which constitute variable consideration) for the nine months ended September 30, 2025, were as follows:

In thousands	Chargebacks, Discounts for Prompt pay and Other allowances	Rebates, Customer Fees/Credits and Co-Pay Assistance	Totals
<b>Balance at December 31, 2024</b>	<u>\$ 276</u>	<u>\$ 707</u>	<u>\$ 983</u>
Provision related to sales made in:			
Current period	418	224	642
Prior periods	—	—	—
Payments and customer credits issued	(328)	(61)	(389)
<b>Balance at March 31, 2025</b>	<u>\$ 366</u>	<u>\$ 870</u>	<u>\$ 1,236</u>
Provision related to sales made in:			
Current period	553	196	749
Prior periods	—	—	—
Payments and customer credits issued	(637)	(185)	(822)
<b>Balance at June 30, 2025</b>	<u>\$ 282</u>	<u>\$ 881</u>	<u>\$ 1,163</u>
Provision related to sales made in:			
Current period	605	570	1,175
Prior periods	—	—	—
Payments and customer credits issued	(407)	(184)	(591)
<b>Balance at September 30, 2025</b>	<u>\$ 480</u>	<u>\$ 1,267</u>	<u>\$ 1,747</u>

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. Trade accounts receivable are recorded at the invoiced amount and are typically non-interest bearing. 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 with 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. For customers that are large specialty distributors, the Company considered the risk of potential credit losses to be low. Sales to other select global distributors have an increased potential for losses. The Company evaluates the risk of credit losses on sales on an individual basis using the above-mentioned criteria. Accounts receivable that are expected to be received past 12 months are recorded as non-current accounts receivable. The Company has determined any financing component of non-current receivables to be immaterial. The Company had a balance in allowance for credit losses of \$3,845 as of September 30, 2025.

#### **Credit Losses**

The Company estimates and records a provision for its expected credit losses related to its trade receivables. The Company considers historical collection rates, the current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer, as the Company determined that risk profile of its customers may vary based on certain characteristics such as credit history, past payment history and geography. Each class of customer component is analyzed for estimated credit losses individually. In doing so, the Company establishes a customer profile, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the life sciences industry to estimate if there are current expected credit losses within its trade receivables based on the trends and the Company's expectation of the future status of such economic and industry-specific factors. Also, specific allowance amounts are established based on review of outstanding invoices to record the appropriate provision for customers that have a higher probability of default.

#### **Cost of Products Sold**

Cost of products sold is related to the Company's product revenues for PEDMARK<sup>®</sup> and consists primarily of product production costs associated with finished goods inventory. Cost of products sold also consists of shipping and other third-party logistics and distribution costs for the Company's product. As of September 30, 2025, the Company capitalized approximately \$2,477 of costs as inventory on the condensed consolidated balance sheet. Of the items capitalized, \$1,437 was capitalized as raw materials, \$851 was capitalized as work in process, \$189 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, 2025, the Company had \$21,947 in cash, savings and money market accounts (\$26,634 at December 31, 2024). 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, 2025 and December 31, 2024, 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 variable 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.

### **Common Shares and Warrants**

As of September 30, 2025, the Company has 111 warrants with a weighted average strike price of \$8.00 outstanding to purchase common shares that have a weighted average life of 1.93 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<sup>®</sup>. In the U.S., the customers are a limited group of specialty distributors, and direct customers, 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 low, 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, 2025, 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.

### 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, stock options and warrants, if dilutive, as determined using the if-converted method and treasury methods.

### Recent Accounting Pronouncements

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 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 condensed financial statements.

In November 2024, the FASB issued ASU 2024-03, “Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses,” which requires disclosure of additional disaggregated information about significant expenses within relevant income statement captions, such as purchases of inventory, employee compensation, depreciation, amortization and depletion. The new guidance is effective for annual periods beginning after December 15, 2026, and interim periods within annual periods beginning after December 15, 2027. We are currently evaluating the impact of this standard on our consolidated condensed 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 share 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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
<b>Numerator:</b>				
Net (loss)/income	\$ (638)	\$ (5,735)	\$ (4,954)	\$ 1,549
<b>Denominator:</b>				
Weighted-average common shares, basic	27,889	27,371	27,711	27,371
Dilutive effect of stock options	—	—	—	620
Dilutive effect of warrants	—	—	—	24
Weighted-average common shares, diluted	27,889	27,371	27,711	28,015
<b>Net (loss)/income per share, basic</b>	<b>\$ (0.02)</b>	<b>\$ (0.21)</b>	<b>\$ (0.18)</b>	<b>\$ 0.06</b>
<b>Net (loss)/income per share, diluted</b>	<b>\$ (0.02)</b>	<b>\$ (0.21)</b>	<b>\$ (0.18)</b>	<b>\$ 0.06</b>

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:

	Diluted Earnings Per Share Three Months Ended September 30,		Diluted Earnings Per Share Nine Months Ended September 30,	
	2025	2024	2025	2024
Options to purchase common shares	5,915	393	5,915	4,835
Convertible debt to purchase common shares	3,761	—	3,761	—
Restricted share units to purchase common shares	419	78	419	367
Performance share units to purchase common shares	244	—	244	—
Warrants to purchase common shares	111	24	111	126

#### 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, 2025, and 2024, there were 39 warrants exercised and no warrants were issued. Outstanding warrants have a weighted average life of 1.93 years on September 30, 2025. The following tables detail the Company's warrant activity for the three and nine months ended September 30, 2025, and 2024, respectively:

Investor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price \$USD
<b>Outstanding December 31, 2024</b>	<b>150</b>	<b>\$ 7.79</b>
Issued	—	—
<b>Outstanding March 31, 2025</b>	<b>150</b>	<b>7.79</b>
Issued	—	—
<b>Outstanding June 30, 2025</b>	<b>150</b>	<b>7.79</b>
Exercised <sup>1</sup>	(39)	6.90
<b>Outstanding September 30, 2025</b>	<b>111</b>	<b>\$ 8.00</b>

1. On July 17, 2025 Bridge Bank opted for a cashless exercise of 39 warrants. Net shares of 9 were issued.

##### Equity Incentive Plan

The Company maintains the 2020 Equity Incentive Plan (the "2020 Plan" or the "Plan"), which is administered by the Compensation Committee of the Board of Directors. The 2020 Plan provides for the issuance of stock options, restricted share units ("RSUs"), and other equity-based awards to employees, directors, officers, and consultants of the Company. The Compensation Committee is responsible for determining eligible participants and approving individual award grants under the 2020 Plan.

On April 24, 2025, the Company's Board of Directors approved an amendment to the Plan to: (i) increase the number of common shares available for issuance under the Plan (excluding common shares issued prior to the date of the meeting pursuant to the exercise of options and vesting of RSUs) to 8,500 common shares, representing approximately 30.8% of the total issued and outstanding common shares as of the date of the circular; and (ii) include provisions for an employee stock purchase program. The amendment was subsequently approved by the Company's shareholders on June 3, 2025.

Prior to this amendment, the maximum number of equity instruments issuable under the Plan, together with the Company's prior stock option plan, was limited to 25% of the Company's issued and outstanding common shares. Based on the then-current outstanding share count, this equated to a maximum of 6,825 common shares available for issuance.

All stock options granted under the Plan have an exercise price equal to the fair value of the Company's common shares on the date of grant. Options generally vest over a period of up to three years and are exercisable for a period of up to ten years from the grant date. Awards under the Plan may be denominated in either U.S. or Canadian dollars.

The Company recognizes stock-based compensation expense for all share-based awards granted to employees and non-employees based on the fair value of the awards on the grant date. The following table summarizes stock-based compensation expense related to equity awards:

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Stock-based expense recognized	\$ 2,219	\$ 1,821	\$ 4,511	\$ 3,937
<b>Total option expense recognized</b>	<b>\$ 2,219</b>	<b>\$ 1,821</b>	<b>\$ 4,511</b>	<b>\$ 3,937</b>

### Stock Option Activity

The following is a summary of option activity for the three and nine months ended September 30, 2025.

Options	Number of Options (thousands)	Weighted-Average Exercise Price \$USD
Outstanding at December 31, 2024	5,855	\$ 6.22
Granted	180	6.50
Exercised	(55)	5.00
Forfeited	(123)	6.94
Outstanding at March 31, 2025	<b>5,857</b>	<b>\$ 6.22</b>
Granted	318	7.41
Exercised	(52)	5.08
Forfeited	(45)	4.23
Outstanding at June 30, 2025	<b>6,078</b>	<b>\$ 6.31</b>
Granted	125	9.11
Exercised	(257)	5.51
Forfeited	(31)	6.94
<b>Outstanding at September 30, 2025</b>	<b>5,915</b>	<b>\$ 6.38</b>

Of the 5,915 options granted and outstanding at September 30, 2025, 4,493 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, 2025
Expected dividend	0.00%
Risk free rate	3.93- 4.19%
Expected volatility	71.04 - 161.67%
Expected life	1.5 - 6.0 years

**Performance-Based Units**

In May and August 2025, the Board of Directors approved PSU grants whereby vesting depends on certain revenue performance milestones during the year ending December 31, 2025. The Company estimates the likelihood of achievement of performance milestones for all PSU awards at the end of each reporting period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. As of September 30, 2025, the Company deems the achievement of the performance milestones to be probable.

The following table summarizes PSU activity under the 2020 Plan during the three and nine months ended September 30, 2025:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2025	—	\$ —
Granted	100	6.62
Vested	—	—
Forfeited	—	—
Unvested balance at June 30, 2025	<u>100</u>	<u>\$ 6.62</u>
Granted	150	8.20
Vested	—	—
Forfeited	(6)	6.55
<b>Unvested balance at September 30, 2025</b>	<b><u>244</u></b>	<b><u>\$ 7.57</u></b>

**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, 2025. During the three and nine months ended September 30, 2025, there were 66 and 181 RSUs released from restriction, respectively. Standard vesting of RSUs is over three years with 1/3 vesting on the first anniversary date of the grant and then 1/24 on the last day of each subsequent month. The Compensation Committee may also award RSUs with alternative vesting.

RSUs Current Year	Number of Restricted Share Units (thousands)
<b>Outstanding at December 31, 2024</b>	<b>324</b>
Awarded	283
Released	(13)
Forfeited	(5)
<b>Outstanding at March 31, 2025</b>	<b><u>589</u></b>
Awarded	—
Released	(102)
Forfeited	(2)
<b>Outstanding at June 30, 2025</b>	<b><u>485</u></b>
Awarded	—
Released	(66)
Forfeited	—
<b>Outstanding at September 30, 2025</b>	<b><u>419</u></b>

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, 2025 and December 31, 2024							
	(in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2025	2024	2025	2024	2025	2024	2025	2024
<b>Assets</b>								
Cash and cash equivalents	\$ 1,659 <sup>(1)</sup>	\$ 2,020 <sup>(1)</sup>	\$ 20,288	\$ 24,614	\$ —	\$ —	\$ 21,947	\$ 26,634
Processa common shares	\$ 1 <sup>(2)</sup>	\$ 2 <sup>(2)</sup>	\$ —	\$ —	\$ —	\$ —	\$ 1	\$ 2

(1) The Company held approximately \$1,659 in cash accounts as of September 30, 2025, of which approximately \$440 was held in foreign currencies (translated into U.S. dollars). As of December 31, 2024, the Company held approximately \$2,020 in cash of which approximately \$363 was in foreign currencies (translated into U.S. dollars).

(2) The Company holds 51 unrestricted common shares of Processa Pharmaceuticals, Inc. (NASDAQ:PCSA), which it received as part of a royalty arrangement in 2020.

## 6. Commitments and Contingencies

### Litigation

#### 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<sup>®</sup> (sodium thiosulfate solution) that contained Paragraph IV Certifications on two of our patents covering PEDMARK<sup>®</sup>: 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<sup>®</sup>. 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<sup>®</sup>'s FDA approval date of September 20, 2022, which is September 20, 2029.

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 US '190 Patent, the US '728 Patent, and the US '984 Patent. On April 20, 2023, we filed an Amended Complaint to assert infringement of the US '728 Patent and the US '984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the "US '793 Patent") covering the formulation of the PEDMARK<sup>®</sup> 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 US '793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the US '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 US '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 "US '018 Patent") covering a method of using our PEDMARK<sup>®</sup> 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 "US '530 Patent") covering a method of using our PEDMARK<sup>®</sup> 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 "US '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 US '018 Patent and the US '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, which we filed on September 16, 2024.

In coordination with the Third Amended Complaint, we entered into a covenant not to sue CIPLA on the US '363 Patent, US '728 Patent, US '984 Patent, US '530 Patent, and US '604 Patent, subject to the limitation that such shall not apply to the extent CIPLA alters the product or formulation described in its FDA ANDA application.

On May 27, 2025, we were granted US 12,311,026 (the "US '026 Patent") covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '026 Patent has an expiration date of July 2039.

On May 27, 2025, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:25-cv-05709), for infringement of the US '026 Patent based on the Cipla entities' ANDA filing. Subsequently, we filed a Motion to Consolidate Case No. 2:25-cv-05709 and Case No. 2:23-cv-00123.

On July 14, 2025, the court granted the Motion to Consolidate Case No. 2:25-cv-05709 with Case No. 2:23-cv-00123. On July 14, 2025, the court issued its Order on Claim Construction on two claim terms in dispute, adopting our proposed constructions for both.

On August 25, 2025, the CIPLA entities filed an Answer and Counterclaims to the complaint, alleging that the '026 Patent was invalid, not infringed, and/or unenforceable.

The suit is ongoing.

## **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 \$559). 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 \$344. Further, certain other Executive Employment Agreements generally provide that if 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.

On August 1, 2023, the Company entered into a second Office Service Agreement (the "Second Office Service Agreement") with Regus to lease office space in Dublin, Ireland. Per the terms of the Second Office Service Agreement, the monthly rent payments are \$2. The Company was required to pay a security deposit of \$5, which is the equivalent of two months rent. The Second Office Service Agreement commenced on August 1, 2023, and terminated 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 month's advance written notice of termination. This lease was terminated.

## **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, 2025, the Company does not offer matching contributions.

## **7. Term Loans**

On August 1, 2022, the Company entered into the SPA with the Petrichor in connection with the issuance of up to \$45,000 of Notes, issuable in multiple tranches. 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 September 20, 2022, which was the date the Company obtained FDA approval of PEDMARK®.

A commitment fee of 2.0% of the Notes was payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 Fennec common shares and half was payable in cash or warrants of 55,498 Fennec common shares, at our election, on the second closing. The warrants are exercisable at a price per share of \$8.11

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and have a term of five years from the date of the grant. The Company elected to have all the commitment fee of the Notes payable in warrants.

On December 4, 2023, the Company closed a third tranche under the SPA in the amount of \$5,000, 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 September 20, 2022, which was the date the Company obtained FDA approval of PEDMARK®.

Also on December 4, 2023, the Company entered into the SPA Amendment with the Petrichor, which, among other things, extended the period that the Company could draw the remaining \$15,000 under the SPA from December 31, 2023, to December 31, 2024. The ability for subsequent draws expired on December 31, 2024.

On December 18, 2024, the Company entered into the Redemption Agreement with Petrichor, pursuant to which the Company repurchased and redeemed Notes in an aggregate principal amount of \$13,000 (consisting of approximately \$11,800 of original principal balance and approximately \$1,271 in PIK interest).

As a result of the Note Redemptions, the First and Third Closing Notes were repurchased and redeemed in full, and, as of September 30, 2025, there remains outstanding Second Closing Notes in the aggregate principal amount (inclusive of PIK interest) of approximately \$19,477.

Cash interest on outstanding principal shall accrue at a rate of prime, plus 4.5% per annum, from the date of funding (11.75% at September 30, 2025, and 12.25% at December 31, 2024, respectively). Cash interest is due on the first business day of each calendar quarter (“Interest Date”). PIK interest will commence on funding date and accrue at a rate of 3.5% per annum. PIK interest stopped accruing on August 24, 2024. All accrued PIK interest remained outstanding and was payable on each Interest Date and added to the outstanding principal amount. The Company has accrued \$1,271 in PIK interest and has classified the PIK interest in long-term liabilities.

The SPA notes are convertible into fully paid, non-assessable share of common shares at any point after their issuance dates and before the maturity date. Any amount of the SPA 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 PSA 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, 2025, are as follows (in thousands):

<b>Years Ending December 31,</b>	<b>Amount</b>
2025	\$ —
2026	—
2027	18,206
Payment in kind interest	1,271
Total future payments	19,477
Less: unamortized debt discount	(100)
Total term loan, net of debt discount	\$ 19,377

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

Debt issuance costs of \$175 were paid in cash for legal fees and to the Investor in 2022 and warrants valued at \$441 were granted 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 and tranche 2, the Company recorded a debt discount of \$314, which was based on a pro-rata allocation of the issue costs to secure the SPA, reducing the capitalized amount by the same amount. The debt discount is being amortized over the life of the SPA.

## 8. 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, 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 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 million or approximately \$43.2 million, which was paid to Fennec on March 15, 2024, (ii) up to €210 million (or approximately \$230 million) 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 Norgine License 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, 2025, the Company did not recognize any milestone 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 Norgine. A portion that represents the license was recognized immediately and is recorded within selling and marketing expense in the consolidated statements of operations. As of September 30, 2025, \$743 in incremental cost was capitalized.

## 9. Segment Reporting

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment principally in the United States.

Fennec's chief operating decision maker is the senior executive team that includes the chief executive officer and chief financial officer. The chief operating decision maker uses net loss to evaluate income generated from segment assets (return on assets) in deciding whether to reinvest profits into the single segment or any other part of the entity, such as for acquisitions or to pay dividends.

The accounting policies of the operating segment are the same as those described in Note 2, Significant Accounting Policies. The chief operating decision maker evaluates the performance of the operating segment and allocates resources based on net loss that also is reported on the consolidated income statement as net loss. The measure of the operating segment assets is reported on the consolidated balance sheet as total assets.

The chief operating decision maker uses net loss to monitor budget versus actual results and to analyze cash flows in assessing performance of the segment and allocating resources. The significant expenses are presented in the Company's Statements of Operations.

## 10. Subsequent Events

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

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

### Caution Concerning Forward-Looking Statements

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 26, 2025 (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<sup>®</sup>. On September 20, 2022, we received approval from the FDA for PEDMARK<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> in the U.S. In addition, in January 2023, PEDMARK<sup>®</sup> 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<sup>®</sup> (known as PEDMARK<sup>®</sup> in the U.S.) Further, the decision included the receipt of a PUMA in the EU with up to 8 years of data exclusivity plus 2 years of market protection. In March 2024, the Company announced an exclusive licensing agreement with Norgine, which will commercialize PEDMARQSI<sup>®</sup> in Europe, Australia and New Zealand. 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 announced the launch of Germany and the U.K. in early 2025.

In the U.S., we sell PEDMARK<sup>®</sup> through an experienced field force. Further, the Company utilizes 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<sup>®</sup>.

We received Orphan Drug Exclusivity for PEDMARK<sup>®</sup> 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<sup>®</sup> in the FDA 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<sup>®</sup> 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 “US ‘604 Patent”) covering methods of using our PEDMARK<sup>®</sup> 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<sup>®</sup>. Additionally, on May 27, 2025, we were granted US 12,311,026 (the “US ‘026 Patent”) covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US ‘026 Patent has an expiration date of July 2039.

### **PEDMARK<sup>®</sup> Product Overview**

PEDMARK<sup>®</sup> 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 cancer patients 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.

In the United States, PEDMARK<sup>®</sup> is the first and only therapy approved to mitigate the risk of ototoxicity associated with cisplatin in pediatric patients aged one month and older with localized, non-metastatic solid tumors. Further, the National Comprehensive Cancer Network (NCCN) recommend the use of PEDMARK<sup>®</sup> to reduce the risk of cisplatin-induced ototoxicity in patients with localized, non-metastatic solid tumors (category 2A) for Adolescent and Young Adult (AYA) Oncology. As of January 2025, all medical compendia have incorporated Fennec’s clinical updates, and AHFS, the largest online platform for pharmacists, has updated its content to reflect and differentiate PEDMARK<sup>®</sup> in accordance with its labeling.

PEDMARK<sup>®</sup> is the first and only FDA- and EMA-approved agent designed to reduce the risk of cisplatin-induced hearing loss (CIO) in children with localized solid tumors. The strategic imperatives driving the execution of PEDMARK<sup>®</sup>’s strategy include increasing awareness of unmet patient needs and emphasizing the importance of preventing CIO among oncologists. A key goal is to establish PEDMARK<sup>®</sup> as the standard of care (SOC) for all CIO prevention. Additionally, efforts focus on expanding adoption beyond oncologists by ensuring healthcare providers (HCPs) gain confidence in and have positive experiences with PEDMARK<sup>®</sup>. Ensuring seamless access for advocacy groups, payers, and providers is also a priority, along with activating patients and caregivers through disease education to drive demand for PEDMARK<sup>®</sup>. Key activities supporting these objectives include an expanded sales team with a strong track record in both academic and

community settings, partnerships with group purchasing organizations, and specialty pharmacy offerings such as home infusions, white bag delivery, and direct billing. Furthermore, digital materials, a digital speaker bureau to engage pediatric oncologists, audiologists, nurses, and pharmacists, along with a patient access services hub and ongoing support from advocacy groups, are all integral components of the strategy.

In the U.S. and Europe, it is estimated that more than 10,000 pediatric patients may receive platinum-based chemotherapy on an annual basis. The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. PEDMARK® is the first and only therapy approved to mitigate the risk of ototoxicity associated with cisplatin, a form of platinum based chemotherapy, in pediatric patients aged one month and older with localized, non-metastatic solid tumors. Beyond the use of PEDMARK®, 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.

The U.S. pediatric oncology landscape includes approximately 200 targeted pediatric hospital centers, such as those within the Children's Oncology Group (COG), National Cancer Institute (NCI), and National Comprehensive Cancer Network (NCCN) institutions. Around 80% of pediatric cancer patients receive treatment at these key centers.

The Adolescent and Young Adult (AYA) oncology patient is defined as an individual between the ages of 15 and 39 at the time of initial cancer diagnosis. In the U.S., Fennec estimates that approximately 20,000 cisplatin chemotherapy patients are treated annually with the primary tumor types of thyroid cancer, breast cancer, germ cell cancer and testicular cancer.

The U.S. Adolescent and Young Adult (AYA) oncology landscape is shaped by a combination of academic and community centers across the nation. Academic institutions play a critical role in establishing the treatment framework, with 72 NCI-designated academic centers treating approximately 20% of AYA oncology patients. In contrast, around 80% of patients are treated at 3,750 community centers throughout the country.

### **Cisplatin Induced Ototoxicity (“CIO”)**

Cisplatin and other platinum compounds are essential chemotherapeutic agents for the treatment of many pediatric and adult 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 patients 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.

It is estimated that greater than 50% of pediatric patients may suffer permanent hearing loss as a result of CIO and approximately 40-80% of adult patients may suffer permanent hearing loss as a result of CIO.

### **European Commission Marketing Authorization**

PEDMARQSI® (PEDMARK® brand name in Europe.) received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

As previously noted, in March 2024, we entered into an agreement with Norgine, a leading European specialist pharmaceutical company. This is an exclusive licensing agreement under which Norgine will commercialize PEDMARQSI® in Europe, Australia and New Zealand. PEDMARQSI® is the first and only approved therapy in the EU and U.K. for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic solid tumors.

In early 2025, Norgine announced the launch of PEDMARQSI<sup>®</sup> in Germany and the U.K.

### Tariffs and One Big Beautiful Bill Act

In addition, the U.S. and other countries have recently imposed, and may continue to impose, new tariffs. While pharmaceuticals are largely exempt from the recently imposed U.S. tariffs, such exemptions may be terminated or may not apply to any future tariffs. Additionally, pharmaceuticals are not exempt from certain tariffs recently imposed outside of the U.S. We continue to evaluate the impacts of tariffs on our business and results of operations. Based on current information, we do not believe the impact of tariffs on our business, financial condition or results of operations will be material.

In July 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company is currently evaluating the impact of the OBBBA on the Company’s consolidated condensed financial statements and related disclosures

### Results of Operations

Three months ended September 30, 2025 versus three months ended September 30, 2024:

In thousands of U.S. Dollars	Three Months Ended September 30, 2025	%	Three Months Ended September 30, 2024	%	Change
PEDMARK product sales, net	\$ 12,462		\$ 6,974		\$ 5,488
Operating expenses:					
Cost of product sales	660	5 %	1,357	11 %	(697)
Research and development	29	1 %	97	1 %	(68)
Selling and marketing	5,210	41 %	4,601	38 %	609
General and administration	6,752	53 %	6,121	50 %	631
Total operating expense	12,651	100 %	12,176	100 %	475
Loss from operations	(189)		(5,202)		5,013
Unrealized loss on securities	—		(3)		3
Amortization expense	(12)		(21)		9
Interest expense	(586)		(1,025)		439
Unrealized foreign exchange loss	(3)		—		(3)
Interest income	152		516		(364)
Net loss	\$ (638)		\$ (5,735)		\$ 5,097

- The Company recorded net product sales of \$12,462 in the third quarter of 2025 compared to \$6,974 in the same product in 2024 as the Company increased market penetration and access for PEDMARK<sup>®</sup> and as the Company expanded its focus to the adolescent and young adult (AYA) population. Further, the Company recorded \$70 product sales related to the Norgine royalties in the three months ended September 30, 2025.
- Selling and marketing expenses include distribution costs, logistics, shipping and insurance, advertising, wages commissions and out-of-pocket expenses. We recorded \$5,210 in selling and marketing expenses for the three-month period ended September 30, 2025, as compared to \$4,601 for the same period in 2024. The increase is largely related to the Company’s increased commercial and marketing efforts in the United States.
- There was a \$631 increase in general and administrative expenses for the three-month period ended September 30, 2025 compared to the same period in 2024.

- Interest expense decreased by \$439 for the three-month period ended September 30, 2025, compared to the same period in 2024. The decrease was driven mainly by lower long-term debt due to Company's debt paydown of \$13,000 in December 2024.
- Interest income decreased in the three-month period ended September 30, 2025, as compared to the same period in 2024 by \$364, due to lower average cash balances in money market accounts for the comparable periods.

Nine months ended September 30, 2025, versus nine months ended September 30, 2024:

In thousands of U.S. Dollars	Nine Months Ended September 30, 2025	%	Nine Months Ended September 30, 2024	%	Change
PEDMARK product sales, net	\$ 30,865		\$ 21,655		\$ 9,210
Licensing revenue	—		17,958		(17,958)
Total revenue	30,865		39,613		(8,748)
Operating expenses:					
Cost of product sales	2,000	6 %	2,515	7 %	(515)
Research and development	230	1 %	257	1 %	(27)
Selling and marketing	12,510	36 %	14,482	40 %	(1,972)
General and administration	19,853	57 %	18,857	52 %	996
Total operating expenses	34,593	100 %	36,111	100 %	(1,518)
(Loss) / income from operations	(3,728)		3,502		(7,230)
Unrealized loss on securities	(2)		(14)		12
Amortization expense	(38)		(64)		26
Interest expense	(1,772)		(3,103)		1,331
Unrealized foreign exchange gain/(loss)	27		(55)		82
Interest income	559		1,283		(724)
Net (loss) / income	\$ (4,954)		\$ 1,549		\$ (6,503)

- The Company recorded net product sales of \$30,865 in the first three quarters of 2025 compared to \$21,655 in the same product in 2024 as the Company increased market penetration and access for PEDMARK® and as the Company expanded its focus to the adolescent and young adult (AYA) population. For the nine months ended September 30, 2025 the Company recorded \$390 in Norgine royalties within product sales. Further, the Company recorded \$17,958 in licensing revenue related to the Norgine transaction in 2024.
- We recorded \$12,510 in selling and marketing expenses for the nine-month period ended September 30, 2025, as compared to \$14,482 for the same product in 2024. The decrease is largely related to the elimination of European pre commercial activities in 2024 which were completed after the Norgine transaction offset by increased commercial infrastructure spending in the United States including personnel and marketing expenses..
- There was a \$996 increase in general and administrative expenses for the nine-month period ended September 30, 2025 compared to the same period in 2024. There was an increase in the comparable periods in the following expense categories: salaries with increased headcount; consulting and professional costs; and intellectual property expenses related to ongoing patent litigation.
- Amortization expense decreased by \$26 for the nine-month period ended September 30, 2025 as compared to the same period in 2024.
- Interest expense decreased by \$1,331 for the nine-month period ended September 30, 2025, compared to the same period in 2024. The decrease was driven mainly by lower debt balance on long-term debt due to Company's debt paydown of \$13,000 in December 2024.

- Interest income decreased in the nine-month period ended September 30, 2025, as compared to the same period in 2024 by \$724, due to lower average cash balances in money market accounts for the comparable periods.

**Liquidity and Capital Resources**

<b>Selected Asset and Liability Data (thousands):</b>	<b>As of September 30, 2025</b>	<b>As of December 31, 2024</b>
Cash and equivalents	\$ 21,947	\$ 26,634
Other current assets	24,117	17,490
Current liabilities	9,815	6,919
Working capital <sup>(1)</sup>	36,249	37,205
<sup>(1)</sup> [Current assets – current liabilities]		
<b>Selected Equity:</b>		
Common stock and additional paid in capital	218,901	212,566
Accumulated deficit	(224,636)	(219,681)
Stockholders' deficit	(4,492)	(5,872)

- There was a \$4,687 net decrease in cash and cash equivalents between September 30, 2025, and December 31, 2024. The net decrease was primarily the result of cash operating expenses and the timing of working capital collections as the Company's net sales increased.
- The increase in other current assets of \$6,627 between September 30, 2025, and December 31, 2024, primarily relates to an increase in accounts receivable from increased net product sales during the period.
- Current liabilities at September 30, 2025, increased \$2,896 compared to December 31, 2024.
- Working capital decreased by \$956 between September 30, 2025, and December 31, 2024.

The following table illustrates a summary of cash flows data for the nine-month periods of September 30, 2025 and 2024:

<b>Selected Cash Flow Data (dollars and shares in thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2025</b>	<b>2024</b>
Net cash (used in)/provided by operating activities	\$ (6,511)	\$ 28,454
Net cash provided by investing activities	—	—
Net cash provided by financing activities	1,824	(1,403)
Net cash flow	\$ (4,687)	\$ 27,051

The net cash used in operating activities for the nine-month period ended September 30, 2025 was approximately \$6,511 as compared to \$28,454 net cash provided by operating activities during the same period in 2024. There was an increase in net loss of \$6,108 in the nine-month period ended September 30, 2025, as compared to the same period in 2024. The comparable decrease in net cash flow is primarily a result of the proceeds received from the Norgine transaction during 2024 of approximately \$43,200.

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, 2025 and December 31, 2024 was as follows (in thousands):

Outstanding Share Type	September 30, 2025	December 31, 2024	Change
Common shares	28,062	27,527	535
Warrants	111	150	(39)
RSUs	419	324	95
PSUs	244	—	244
Stock options	5,915	5,855	60
Total	34,751	33,856	895

### 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, 2025, we had approximately \$1,660 in our cash accounts and \$20,288 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 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, 2025.

## **Credit Losses**

The Company estimates and records a provision for its expected credit losses related to its trade receivables. The Company considers historical collection rates, the current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses. However, because of the short time to the expected receipt of accounts receivable, the Company believes that the carrying value, net of excepted losses, approximates fair value and therefore, relies more on historical and current analysis of its trade receivables.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer, as the Company determined that risk profile of its customers is consistent based on the life sciences industry. Each class of customer component is analyzed for estimated credit losses individually. In doing so, the Company establishes a customer profile, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the life sciences industry to estimate if there are current expected credit losses within its trade receivables based on the trends and the Company's expectation of the future status of such economic and industry-specific factors. Also, specific allowance amounts are established based on review of outstanding invoices to record the appropriate provision for customers that have a higher probability of default.

## **Revenue Recognition**

Under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, we recognize 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.

## **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).

### 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 periods ended September 30, 2025, we used the following weighted average assumptions:

<b>Black-Scholes Model Assumptions</b>	<b>Valuation Assumptions September 30, 2025</b>
Expected dividend	0.00%
Risk free rate	3.93- 4.19%
Expected volatility	71.04 - 161.67%
Expected life	1.5 - 6.0 years

### Performance-Based Units

In May and August 2025, the Board of Directors approved PSU grants whereby vesting depends on certain revenue performance milestones over the next year. The Company estimates the likelihood of achievement of performance milestones for all PSU awards at the end of each reporting period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. As of September 30, 2025, the Company deems the achievement of the performance milestones to be probable.

### 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.

### Newly Adopted and Recent Accounting Pronouncements

Refer to Note 2, "Significant Accounting Policies - Recent Accounting Pronouncements" to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

### **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, 2025. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file 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 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, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2025, the Company's disclosure controls and procedures were effective.

#### **Changes in Internal Control over Financial Reporting**

There were no changes to the Company's internal control over financial reporting during the quarter ended September 30, 2025, that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **Inherent Limitation on the Effectiveness of Internal Controls**

The effectiveness of any system of internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting can only provide reasonable, not absolute, assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure that such improvements will be sufficient to provide us with effective internal control over financial reporting.

## **PART II: OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

#### *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 contained 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.

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 US ‘190 Patent, the US ‘728 Patent, and the US ‘984 Patent. On April 20, 2023, we filed an Amended Complaint to assert infringement of the US ‘728 Patent and the US ‘984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the “US ‘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 US ‘793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the US ‘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 US ‘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 “US ‘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 “US ‘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 “US ‘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 US ‘018 Patent and the US ‘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, which we filed on September 16, 2024.

In coordination with the Third Amended Complaint, we entered into a covenant not to sue CIPLA on the US ‘363 Patent, US ‘728 Patent, US ‘984 Patent, US ‘530 Patent, and US ‘604 Patent, subject to the limitation that such shall not apply to the extent CIPLA alters the product or formulation described in its FDA ANDA application.

On May 27, 2025, we were granted US 12,311,026 (the “US ‘026 Patent”) covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US ‘026 Patent has an expiration date of July 2039.

On May 27, 2025, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:25-cv-05709), for infringement of the US ‘026 Patent based on the Cipla entities’ ANDA filing. Subsequently, we filed a Motion to Consolidate Case No. 2:25-cv-05709 and Case No. 2:23-cv-00123.

On July 14, 2025, the court granted the Motion to Consolidate Case No. 2:25-cv-05709 with Case No. 2:23-cv-00123.

On July 14, 2025, the court issued its Order on Claim Construction on two claim terms in dispute, adopting our proposed constructions for both.

On August 25, 2025, the CIPLA entities filed an Answer and Counterclaims to the complaint, alleging that the '026 Patent was invalid, not infringed, and/or unenforceable.

The suit is ongoing.

**Item 1A. Risk Factors.**

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 26, 2025 (the "Annual Report"), includes a detailed discussion of our risk factors under the heading "PART I, Item 1A – Risk Factors." You should carefully consider the risk factors discussed in our Annual Report, as well as other information in this Quarterly Report. Any of these risks could cause our business, financial condition, results of operations and future growth prospects to suffer. We are not aware of any material changes from the risk factors previously disclosed.

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Rosty Raykov, a current member of our Board of Directors, adopted a trading arrangement on September 19, 2025, which is intended to satisfy the Rule 10b5-1 affirmative defense. This trading arrangement covers the disposition of up to 109,184 shares of the Company's common shares, and will terminate on June 9, 2026, 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 13, 2025, we issued a press release announcing our financial results for the quarter ended September 30, 2025. 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**

<b>Exhibit No.</b>	<b>Description</b>
31.1	<a href="#">Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
31.2	<a href="#">Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>

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32.1	<a href="#">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).</a>
99.1	<a href="#">Press Release for Quarter September 30, 2025 (filed herewith).</a>
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 13, 2025

By: /s/ Jeff Hackman

Jeff Hackman  
Chief Executive Officer  
(principal executive officer)

Date: November 13, 2025

By: /s/ Robert Andrade

Robert Andrade  
Chief Financial Officer  
(principal financial and chief accounting officer)

**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, 2025 of Fenec 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 13, 2025

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

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**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, 2025, 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 13, 2025

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

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**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, 2025 (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 13, 2025

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

Date: November 13, 2025

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

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## FENNEC PHARMACEUTICALS REPORTS THIRD QUARTER 2025 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

*~ Q3 2025 Total Net Product Revenues of \$12.5 Million, with 79% Year over Year Growth ~*

*~ Q3 2025 Positive Cash Flow from Operations, Cash Position Grew to \$22 Million ~*

*~ Japan Clinical Trial (STS-J01) Preliminary Results Expected in Q4 2025 ~*

**Research Triangle Park, NC, November 13, 2025** – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the third quarter ended September 30, 2025 and provided a business update.

“Today marks an inflection point for Fennec, as we delivered the strongest quarter in our history. Record net product sales, four consecutive quarters of double-digit growth, and our first profitable quarter from operations clearly demonstrate that our strategy is working,” said Jeff Hackman, chief executive officer of Fennec Pharmaceuticals. “What began as a rebuild in the first half of 2025 is now translating into tangible performance. The actions we took to strengthen our commercial organization, drive broader adoption, and reinforce our balance sheet are firmly taking hold. With continued discipline in executing against our strategic priorities, we believe we are well positioned to sustain the growth trajectory of PEDMARK®.”

### **Business Highlights:**

- **Continued Growth Within Key PEDMARK® Accounts:** Last quarter, Fennec announced that one of the largest oncology provider networks added PEDMARK® to its formulary. Since then, adoption has accelerated across numerous accounts within the network, including multiple Adolescent and Young Adult (AYA) patients across several tumor types receiving PEDMARK®. This adoption reflects growing confidence in PEDMARK®’s clinical value and reinforces its potential to help reshape the standard of care for patients receiving cisplatin-based treatment.
- **Clinical Data Generation:** Robust engagement with key opinion leaders underscores strong external validation of PEDMARK® and its potential in broader oncology care. Multiple investigator-initiated studies have already been submitted to Fennec and are currently under review, with several others in advanced contracting or evaluation stages. These collaborations are expected to further strengthen our clinical and commercial foundation, with additional details to be shared as they materialize.
- **STS-J01 in Japan:** In Japan, preliminary results from the investigator-initiated clinical trial (STS-J01) evaluating PEDMARK® are expected in the fourth quarter of 2025. If the data are positive, the Company will pursue registration in Japan and will also explore partnering or licensing opportunities for PEDMARK®.

### **Upcoming Events:**

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- **16th Annual Craig-Hallum Alpha Select Conference:** The management team will host one-on-one investor meetings at the 16<sup>th</sup> Annual Craig-Hallum Alpha Select Conference which will be held on Tuesday, November 18, 2025 at the Sheraton New York Times Square Hotel in New York City.

### **Financial Results for the Third Quarter 2025 Fiscal Year Ended September 30, 2025**

- **Net Product Sales** – For the third quarter of 2025, the Company recorded net product sales of approximately \$12.5 million compared to \$7.0 million in the third quarter of 2024, the highest quarterly net product sales in Fennec’s history. In the first nine months of 2025, net product revenue has surpassed total net sales for full year of 2024. The increase in net product sales is attributable to growth across both new and existing accounts with notable success in adherence of PEDMARK® patients.
- **Selling and Marketing Expenses** – The Company recorded \$5.2 million in selling and marketing expenses in the third quarter of 2025 compared to \$4.4 million in the second quarter of 2025 and \$4.6 million in the third quarter of 2024.
- **General and Administrative (G&A) Expenses** – The Company recorded \$6.8 million in G&A expenses in the third quarter of 2025 compared to \$7.0 million in the second quarter of 2025 and \$6.1 million in the third quarter of 2024.
- **Cash Position** – Cash and cash equivalents were \$21.9 million as of September 30, 2025 compared to \$18.7 million as of June 30, 2025.

### **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, 2025, and management's discussion and analysis of financial condition and results of operations will be available via [www.sec.gov](http://www.sec.gov) and [www.sedar.com](http://www.sedar.com). All values are presented in thousands unless otherwise noted.

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

	<b>Three Months Ended</b>	
	<b>September 30, 2025</b>	<b>September 30, 2024</b>
<b>Revenue</b>		
PEDMARK product sales, net	\$ 12,462	\$ 6,974
<b>Total revenue</b>	<u>12,462</u>	<u>6,974</u>
<b>Operating expenses:</b>		
Cost of product sales	660	1,357
Research and development	29	97
Selling and marketing	5,210	4,601
General and administrative	6,752	6,121
<b>Total operating expenses</b>	<u>12,651</u>	<u>12,176</u>
<b>Loss from operations</b>	<u>(189)</u>	<u>(5,202)</u>
<b>Other (expense)/income</b>		
Unrealized foreign exchange (loss)/gain	(3)	—
Amortization expense	(12)	(21)
Unrealized loss on securities	—	(3)
Interest income	152	516
Interest expense	(586)	(1,025)
Total other expense	<u>(449)</u>	<u>(533)</u>
<b>Net loss</b>	<u>\$ (638)</u>	<u>\$ (5,735)</u>
<b>Basic net loss per common share</b>	<u>\$ (0.02)</u>	<u>\$ (0.21)</u>
<b>Diluted net loss per common share</b>	<u>\$ (0.02)</u>	<u>\$ (0.21)</u>
<b>Weighted-average number of common shares outstanding basic</b>	<u>27,889</u>	<u>27,371</u>
<b>Weighted-average number of common shares outstanding diluted</b>	<u>27,889</u>	<u>27,371</u>

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

	<b>Unaudited September 30, 2025</b>	<b>Audited December 31, 2024</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 21,947	\$ 26,634
Accounts receivable, net	19,343	12,884
Prepaid expenses	1,399	3,080
Inventory	2,477	1,060
Other current assets	898	466
<b>Total current assets</b>	<b>46,064</b>	<b>44,124</b>
<b>Non-current assets</b>		
Non-current accounts receivable, net	2,454	—
Other non-current assets, net of amortization	743	822
<b>Non-current assets</b>	<b>3,197</b>	<b>822</b>
<b>Total assets</b>	<b>\$ 49,261</b>	<b>\$ 47,321</b>
<b>Liabilities and stockholders' deficit</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 5,866	\$ 3,241
Accrued liabilities	3,701	3,428
Contract liability-current	248	248
Operating lease liability - current	—	2
<b>Total current liabilities</b>	<b>9,815</b>	<b>6,919</b>
<b>Long-term liabilities</b>		
Term loan	18,206	18,206
PIK interest	1,271	1,271
Debt discount	(100)	(139)
Contract liability - long-term	24,561	24,561
<b>Total long-term liabilities</b>	<b>43,938</b>	<b>43,899</b>
<b>Total liabilities</b>	<b>53,753</b>	<b>50,818</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' deficit:</b>		
Common stock, no par value; unlimited shares authorized; 27,733 shares issued and outstanding (2024 -27,527)	147,652	145,608
Additional paid-in capital	71,249	66,958
Accumulated deficit	(224,636)	(219,681)
Accumulated other comprehensive income	1,243	1,243
<b>Total stockholders' deficit</b>	<b>(4,492)</b>	<b>(5,872)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 49,261</b>	<b>\$ 44,946</b>

## About Cisplatin-Induced Ototoxicity

Cisplatin and other platinum-based chemotherapies are widely used to treat solid tumors and have been vital in improving survival rates. Unfortunately, these life-saving treatments often result in permanent, irreversible hearing loss, also known as ototoxicity.<sup>i</sup>

Hearing loss from cisplatin treatment is not rare. Studies show that between 60-90% of patients treated with cisplatin may develop hearing loss, depending upon the dose and duration of chemotherapy.<sup>ii</sup> Many of those treated with cisplatin will 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.<sup>iii</sup> Treatment-induced hearing loss can reduce quality of survivorship as it impacts many aspects of life, such as speech and language skills, academic performance, social-emotional development, career potential and the ability to live independently.<sup>iv,v</sup> While audiologic monitoring is recommended to help manage ototoxicity, it is currently underutilized in certain cancer patient populations.

### **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 1 month of age and older 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.

Additionally, PEDMARK is recommended for the adolescent and young adult (AYA) population by the National Comprehensive Cancer Network, or NCCN, with a 2A endorsement.

Approximately 500,000 patients in the U.S. are diagnosed annually with cancers that could be treated with a platinum-based chemotherapy.<sup>vi,vii</sup> The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of those treated will require lifelong hearing aids. Until the FDA approval of PEDMARK, there were no preventative agents for this hearing loss. Patients with hearing loss resulting from cancer treatment have a statistically significant worse quality of life compared with peers who have no hearing loss.<sup>viii,ix</sup>

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.

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**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<sup>2</sup>.

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

The most common adverse reactions ( $\geq 25\%$  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 ( $\geq 25\%$  with difference between arms of  $>5\%$  compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full Prescribing Information for PEDMARK<sup>®</sup> at: [www.PEDMARK.com](http://www.PEDMARK.com).

**About Fennec Pharmaceuticals**

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company committed to the fight against ototoxicity in cancer patients who receive cisplatin-based chemotherapy. Fennec is focused on the commercialization of PEDMARK<sup>®</sup> to reduce the risk of platinum-induced ototoxicity in cancer patients. PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and United Kingdom (U.K.) approval in October 2023 under the brand name PEDMARQSI<sup>®</sup>.

In March 2024, Fennec entered into an exclusive licensing agreement under which Norgine Pharmaceuticals Ltd., a leading European specialist pharmaceutical company, will commercialize PEDMARQSI<sup>®</sup> in Europe, U.K., Australia and New Zealand. PEDMARQSI is now commercially available in the U.K. and Germany.

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. Further, Fennec has patents providing protection for PEDMARK until 2039 in both the U.S. and internationally.

For more information, please visit [www.fennecpharma.com](http://www.fennecpharma.com) and follow on LinkedIn.

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### **Forward Looking Statements**

Except for historical information described in this press release, all other statements are forward-looking. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®/PEDMARQSI®, the market opportunity for and market impact of PEDMARK®/PEDMARQSI®, its potential impact on patients and anticipated benefits associated with its use, future commercial and regulatory milestone and royalty payments from Norgine, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company’s business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company’s patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company’s products will not be as large as expected, the Company’s products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company’s filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2024. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at [www.sec.gov](http://www.sec.gov) and [www.sedar.com](http://www.sedar.com).

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<sup>i</sup> Sheth S et al. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. *Frontiers in Cellular Neuroscience*. 2017, Vol. 11.

<sup>ii</sup> Langer T, am Zehnhoff-Dinnesen A, Radtke S, Meitert J, Zolk O. Understanding platinum-induced ototoxicity. *Trends Pharmacol Sci*. 2013;34(8):458-469

<sup>iii</sup> Landier W. Ototoxicity and Cancer Therapy. *Cancer*. June 2016 Vol. 122, No.11: 1647-1658.

<sup>iv</sup> Clemens E, van den Heuvel-Eibrink MM, Mulder RL, et al. Recommendations for ototoxicity surveillance for childhood, adolescent, and young adult cancer survivors: a report from the International Late Effects of Childhood Cancer Guideline Harmonization Group in collaboration with the PanCare Consortium. *Lancet Oncol*. 2019;20(1):e29-e41

<sup>v</sup> Bass JK, Knight KR, Yock TI, Chang KW, Cipkala D, Grewal SS. Evaluation and management of hearing loss in survivors of childhood and adolescent cancers: a report from the children’s oncology group. *Pediatr Blood Cancer*. 2016;63(7):1152-1162.

<sup>vi</sup> Chattaraj A et al. Cisplatin-Induced Ototoxicity: A Concise Review of the Burden, Prevention, and Interception Strategies. *JCO Oncol Pract*. 2023;19

<sup>vii</sup> Freyer DR et al. Effects of sodium thiosulfate versus observation on development of cisplatin-induced hearing loss in children with cancer (ACCL0431): a multicentre, randomised, controlled, open-label, phase 3 trial. *Lancet Oncol*. 2017;18(1):63-74.

<sup>viii</sup> Rajput K, Edwards L, Brock P, Abiodun A, Simpkin P, Al-Malky G. Ototoxicity-induced hearing loss and quality of life in survivors of paediatric cancer. *Int J Pediatr Otorhinolaryngol*. 2020;138:110401. doi:10.1016/j.ijporl.2020.110401

<sup>ix</sup> Bass JK, Knight KR, Yock TI, Chang KW, Cipkala D, Grewal SS. Evaluation and management of hearing loss in survivors of childhood and adolescent cancers: a report from the children’s oncology group. *Pediatr Blood Cancer*. 2016;63(7):1152-1162.