

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, 2022
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 11, 2022, there were 26,237,726 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)

	<u>September 30, 2022</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 29,752	\$ 21,100
Prepaid expenses	278	1,034
Other current assets	123	253
Total current assets	<u>30,153</u>	<u>22,387</u>
Non-current assets		
Deferred issuance cost, net of amortization	264	27
Total non-current assets	<u>264</u>	<u>27</u>
Total assets	<u>\$ 30,417</u>	<u>\$ 22,414</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,533	\$ 777
Accrued liabilities	394	877
Total current liabilities	<u>2,927</u>	<u>1,654</u>
Long-term liabilities		
Term loan	25,000	5,000
Debt discount	(312)	(12)
Total long-term liabilities	<u>24,688</u>	<u>4,988</u>
Total liabilities	<u>27,615</u>	<u>6,642</u>
Commitments and Contingencies (Note 6)		
Stockholders' equity:		
Common stock, no par value; unlimited shares authorized; 26,238 shares issued and outstanding (2021 - 26,014)	141,309	140,801
Additional paid-in capital	56,593	53,214
Accumulated deficit	(196,343)	(179,486)
Accumulated other comprehensive income	1,243	1,243
Total stockholders' equity	<u>2,802</u>	<u>15,772</u>
Total liabilities and stockholders' equity	<u>\$ 30,417</u>	<u>\$ 22,414</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, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	846	1,242	3,414	4,458
General and administrative	7,053	2,931	13,040	8,558
Loss from operations	(7,899)	(4,173)	(16,454)	(13,016)
Other (expense)/income				
Foreign currency transaction loss	(4)	(1)	(6)	(9)
Amortization expense	(64)	(8)	(79)	(8)
Unrealized (loss)/gain on securities	(27)	39	(126)	137
Interest income	24	13	42	41
Interest expense	(119)	(55)	(234)	(64)
Total other (expense)/income	(190)	(12)	(403)	97
Net loss	\$ (8,089)	\$ (4,185)	\$ (16,857)	\$ (12,919)
Basic net loss per common share	\$ (0.31)	\$ (0.16)	\$ (0.65)	\$ (0.50)
Diluted net loss per common share	\$ (0.31)	\$ (0.16)	\$ (0.65)	\$ (0.50)
Weighted-average number of common shares outstanding basic	26,108	26,007	26,105	26,004
Weighted-average number of common shares outstanding diluted	26,108	26,007	26,105	26,004

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)

	<u>Nine Months Ended</u>	
	<u>September 30,</u> <u>2022</u>	<u>September 30,</u> <u>2021</u>
Cash flows (used in) provided by:		
Operating activities:		
Net loss	\$ (16,857)	\$ (12,919)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt access fees	77	7
Amortization of debt discount	2	1
Unrealized loss/(gain) on securities	126	(137)
Stock-based compensation - consultants	103	9
Stock-based compensation - employees	3,260	2,830
Changes in operating assets and liabilities:		
Prepaid expenses	756	(435)
Other assets	4	—
Accounts payable	1,756	(417)
Accrued liabilities	(483)	84
Net cash used in operating activities	<u>(11,256)</u>	<u>(10,977)</u>
Financing activities:		
Long-term debt	25,000	5,000
Long-term debt paid	(5,000)	—
Debt discount	—	(14)
Capitalized deferred issuance costs	(175)	(42)
Cash paid for taxes on restricted share release	(166)	—
Issuance of shares, options exercise	249	24
Net cash provided by financing activities	<u>19,908</u>	<u>4,968</u>
Increase/(decrease) in cash and cash equivalents	8,652	(6,009)
Cash and cash equivalents - Beginning of period	21,100	30,344
Cash and cash equivalents - End of period	<u>\$ 29,752</u>	<u>\$ 24,335</u>
Non-cash investing and financing activities:		
Warrants issued for long-term debt	<u>\$ 441</u>	<u>\$ —</u>

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

Fennec Pharmaceuticals Inc.
Condensed Consolidated Statements of Stockholders' Equity
Three and Nine Months Ended September 30, 2022, and 2021
(U.S. dollars and shares in thousands)
(Unaudited)

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	26,003	\$ 140,733	\$ 49,234	\$ (162,140)	\$ 1,243	\$ 29,070
Stock options issued to employees	—	—	587	—	—	587
Stock options issued to contractors	—	—	9	—	—	9
Net loss	—	—	—	(4,733)	—	(4,733)
Balance at March 31, 2021	26,003	\$ 140,733	\$ 49,830	\$ (166,873)	\$ 1,243	\$ 24,933
Stock options issued to employees	—	—	1,326	—	—	1,326
Stock option exercise	4	47	(24)	—	—	23
Net loss	—	—	—	(4,001)	—	(4,001)
Balance at June 30, 2021	26,007	\$ 140,780	\$ 51,132	\$ (170,874)	\$ 1,243	\$ 22,281
Stock options issued to employees	—	—	917	—	—	917
Net loss	—	—	—	(4,185)	—	(4,185)
Balance at September 30, 2021	26,007	\$ 140,780	\$ 52,049	\$ (175,059)	\$ 1,243	\$ 19,013

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

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

1. Nature of Business and Going Concern

Fennec Pharmaceuticals Inc., a British Columbia corporation (“Fennec,” the “Company,” “we,” “us,” or “our”), is a commercial stage specialty biopharmaceutical company focused on PEDMARK[®] (sodium thiosulfate injection) for the prevention of platinum-induced ototoxicity in pediatric cancer patients. We have four wholly-owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian company, and Fennec Pharmaceuticals (EU) Limited (“Fennec Limited”), an Ireland company. 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 (“U.S. GAAP”) that are applicable to a going concern, which contemplates that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of business.

During the three and nine months ended September 30, 2022, the Company incurred a loss from operations of \$7,899 and \$16,454, respectively. At September 30, 2022, the Company had an accumulated deficit of \$196,343 and had experienced negative cash flows from operating activities during the nine months ended September 30, 2022 in the amount of \$11,256.

On August 1, 2022, the Company entered into a Securities Purchase Agreement (the “SPA”) with Petrichor Opportunities Fund I LP (the “Creditor”) in connection with the issuance of up to \$45,000 of senior secured floating rate convertible notes (the “Notes”), issuable in multiple tranches (the “Note Financing”). On August 19, 2022, the Company closed on the initial tranche of \$5,000 (the “First Closing Note”) which has an Initial Conversion Price equal to \$8.11 per share, which was calculated based on a 20% premium of the 5-day volume weighted average price of the Company’s common shares as traded on the Nasdaq Capital Market (the “VWAP”) immediately prior to the announcement of the Securities Purchase Agreement (“SPA”) dated August 1, 2022. 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 (the “Second Closing Trigger”).

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

A commitment fee of 2.0% of the Notes is payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 of the Company’s common shares (“First Closing Warrant”) and half is payable in cash or warrants of 55,498 of the Company’s 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 will have a term of five years from the date of the grant. Subsequently, the Company elected to have the all the commitment fee of the Notes paid in warrants.

The Company believes current funds, along with the funds from the Note Financing issued as part of the Creditor financing provide sufficient funding for the Company to carry out its planned activities, including the commencement of commercialization efforts for at least the next twelve months of PEDMARK. The Company also has the ability to obtain additional funds under the Subsequent Closing Notes.

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

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 was not appropriate or if there was a materially adverse event which affected the Company's solvency.

2. Significant Accounting Policies

Basis of presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. 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 U.S. GAAP for annual financial statements. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited 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, 2021. 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, 2021. These unaudited interim condensed consolidated financial statements have been prepared in U.S. dollars. All amounts presented are in thousands except for per share amounts. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the full fiscal year.

Use of estimates

The preparation of financial statements in conformity with U.S. 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 interim condensed consolidated financial statements and the reported amounts of expense during the reporting period. Actual results could differ from those estimates.

In the opinion of management, these unaudited interim condensed consolidated financial statements include all adjustments, which are normal and recurring in nature, necessary for the fair presentation of the Company's financial position at September 30, 2022 and to state fairly the results for the periods presented. The most significant estimates utilized during the three and nine months ended September 30, 2022 include estimates necessary to value grants of various equity instruments to employees and contractors and the warrants issued to the Creditor, as disclosed in Note 4.

New accounting pronouncements

The Company did not adopt any new accounting pronouncements during the quarter ended September 30, 2022.

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, 2022, the Company had \$29,752 in cash, savings and money market accounts (\$21,100 at December 31, 2021). At September 30, 2022, the Company held \$438 in cash of which \$33 (as presented in U.S. dollars) was in Canadian dollars (\$34 at December 31, 2021 as presented in U.S. dollars). At September 30, 2022, the Company held \$29,314 in money market investments. Money market investments typically have minimal risks. While the Company has not experienced any loss or write-down of its money market investments, the amounts it holds in money market accounts are substantially above the \$250 amount insured by the FDIC and may lose value.

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

Inventory

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory costs include third-party contract manufacturing, third-party packaging services and freight. At this time, we primarily use actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires management review of the expiration dates of PEDMARK[®] compared to our forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required, which would be recorded as cost of goods sold in the condensed consolidated statement of operations.

Prior to FDA approval of PEDMARK[®], we incurred expenses for the manufacture of PEDMARK[®] that could potentially be available to support the commercial launch of our products. We will begin to capitalize inventory costs associated with PEDMARK during the fourth quarter of 2022. Management could not determine that FDA approval was probable in advance of the actual event and therefore, could not determine whether its product inventory had a probable future economic benefit. As a result, we did not capitalize any pre-launch inventory.

Financial instruments

Financial instruments recognized on the balance sheets at September 30, 2022 and December 31, 2021 consist of cash and cash equivalents, common shares of Processa Pharmaceuticals, Inc., accounts payable and accrued liabilities, the carrying values of which approximate fair value due to their relatively short time to maturity. 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. As our main purpose is preservation of capital while we endeavor to become cash flow positive through the sale of product, we have chosen to avoid investments of a trading or speculative nature. 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 a maximum-weighted average time to maturity of twelve months.

Product revenue, net

The Company received FDA approval of PEDMARK[®] on September 20, 2022, and will begin recognizing product revenues after the initial product launch of PEDMARK[®] in October 2022.

3. Loss Per Share

Earnings per common share is presented under two formats: basic earnings per common share and diluted earnings per common share. Basic earnings per common share is computed by dividing net income attributable to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of common shares outstanding during the period, plus the potentially dilutive impact of common stock equivalents (i.e. stock options and warrants). Dilutive common share

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

equivalents consist of the incremental common shares issuable upon exercise of stock options and warrants. The following table sets forth the computation of basic and diluted net loss per share:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2022	2021	2022	2021
Numerator:				
Net loss	\$ (8,089)	\$ (4,185)	\$ (16,857)	\$ (12,919)
Denominator:				
Weighted-average common shares, basic	26,108	26,007	26,105	26,004
Dilutive effect of stock options	—	—	—	—
Dilutive effect of warrants	—	—	—	—
Incremental dilutive shares	—	—	—	—
Weighted-average common shares, diluted	26,108	26,007	26,105	26,004
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.16)	\$ (0.65)	\$ (0.50)

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2022	2021	2022	2021
Options to purchase common shares	4,466	3,653	4,466	3,653
Warrants to purchase common shares	150	39	150	39

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, 2022, the Company issued 111 warrants at a strike price of \$8.11. The Company capitalized \$441 in non-cash expense, and cash expense of \$175 associated with issuing the SPA. During the three and nine month ended September 30, 2022, there were no warrants exercised. Outstanding warrants have a weighted average life of 5.30 years on September 30, 2022. The following tables detail the Company's warrant activity for the three and nine months ended September 30, 2022:

Creditor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price
Outstanding December 31, 2021	39	\$ 6.80
Issued	—	—
Outstanding March 31, 2022	39	\$ 6.80
Issued	—	—
Outstanding June 30, 2022	39	\$ 6.80
Issued	111	8.11
Outstanding September 30, 2022	150	\$ 7.30

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

Equity Incentive Plan

The Compensation Committee of the Board of Directors administers the Company’s equity incentive plan (the “Plan”). The Compensation Committee designates eligible participants to be included under the Plan and approves the number of equity instruments to be granted from time to time under the Plan. Currently, the maximum number of equity instruments issuable under the Plan, together with the Company’s prior stock option plan, is twenty-five percent (25%) of the total number of issued and outstanding common shares. Based upon the current shares outstanding, a maximum of 6,559 shares of common stock are authorized for issuance pursuant to stock options or other equity awards granted under the Plan. For all options issued under the Plan, the exercise price is the fair value of the underlying shares on the date of grant. All options vest within three years or less and are exercisable for a period of ten years from the date of grant. The Plan allows the issuance of Canadian and U.S. dollar grants. The table below outlines recognized contractor and employee expense from equity awards for the three and nine month periods ended September 30, 2022 and 2021.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2022	2021	2022	2021
Contractor options expense recognized	\$ 34	\$ —	\$ 103	\$ 9
Employee options expense recognized	1,853	917	3,260	2,830
Total option expense recognized	\$ 1,887	\$ 917	\$ 3,363	\$ 2,839

Stock Option Activity

The following is a summary of option activity for the three and nine months ended September 30, 2022, for stock options denominated in U.S. dollars. Since August of 2020, there have been no Canadian denominated options outstanding.

<u>US Denominated Options</u>	<u>Number of</u> <u>Options (thousands)</u>	<u>Weighted-Average</u> <u>Exercise Price</u>
Outstanding at December 31, 2021	4,259	\$ 5.13
Granted	200	5.64
Exercised	(26)	0.58
Forfeited	(382)	6.13
Outstanding at March 31, 2022	4,051	5.34
Granted	305	5.71
Exercised	(19)	2.38
Outstanding at June 30, 2022	4,337	5.14
Granted	310	6.93
Exercised	(151)	1.25
Forfeited	(30)	5.59
Outstanding at September 30, 2022	4,466	\$ 5.33

During the three and nine month periods ended September 30, 2022, there were 310 and 815 options granted, respectively. During the three and nine month periods ended September 30, 2022, there were 151 and 196 exercises of options, respectively. This resulted in a cash inflow of \$188 and \$249, respectively. During the three and nine month periods ended September 30, 2022, there were 30 and 412 option grant forfeitures by departing employees. Of the 4,466 U.S. denominated options granted and outstanding at September 30, 2022, 3,448 are fully vested and exercisable.

The value of options and warrants 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.

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

Black-Scholes Model Assumptions	Valuation Assumptions September 30, 2022
Expected dividend	0.00%
Risk free rate	1.18 - 4.11%
Expected volatility	67 - 74%
Expected life	5 - 6.0 years

Restricted Share Units Activity

The Plan allows for the issuance of restricted share units ("RSU's"). The following is a summary of RSU activity for the three and nine months ended September 30, 2022. During the three and nine month ended September 30, 2022, there were 20 and 28 RSU's released from restriction, respectively. During the nine months ended September 30, 2022, there were 88 RSU's forfeited by departing employees. All RSU's vest over one to three years.

US Denominated RSUs	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2021	219
Awarded	—
Forfeited	(88)
Outstanding at March 31, 2022	131
Awarded	—
Released	(8)
Outstanding at June 30, 2022	123
Awarded	—
Released	(20)
Outstanding at September 30, 2022	103

The value of RSU's issued was estimated using the share price on the date of the award multiplied by the number of 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 U.S. 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.

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	Fair Value Measurement at September 30, 2022 and December 31, 2021							
	(in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2022	2021	2022	2021	2022	2021	2022	2021
Assets								
Cash and cash equivalents	438 (1)	82 (1)	29,314	21,018	—	—	29,752	21,100
Processa common shares	—	—	114 (2)	240 (2)	—	—	114	240

- (1) The Company held approximately \$438 in cash as of September 30, 2022, of which approximately \$33 was in Canadian funds (translated into U.S. dollars). As of December 31, 2021, the Company held approximately \$82 in cash of which approximately \$34 was in Canadian funds (translated into U.S. dollars).
- (2) The Company holds 46 unrestricted common shares of Processa Pharmaceuticals, Inc. (NASDAQ:PCSA) (“Processa”). The Company received another 5 restricted common shares of Processa on October 20, 2022 which will become unrestricted one year after receipt. The Company originally applied a 20%, 30% and 40% liquidity discount to the shares and will mark to market at each balance sheet date. The Company will also adjust the liquidity discounts being applied to the share valuation to appropriately reflect the passage of time and the existence of any restrictions on the shares. Valuation of the shares at September 30, 2022 had a 0%, 0% and 15% liquidity discount applied to the 41, 5 and 5 share tranches, respectively.

6. Commitments and Contingencies

Oregon Health & Science University Agreement

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

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

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

Securities Class Action Suit

Chapman v. Fennec Pharmaceuticals Inc. et al.

On September 3, 2020, plaintiff Jim Chapman filed a putative federal securities class action lawsuit against the Company, our Chief Executive Officer, Rostislav Raykov, and Chief Financial Officer, Robert Andrade, in the United States District Court for the Middle District of North Carolina, captioned *Chapman v. Fennec Pharmaceuticals Inc. et al.*, Case No. 1:20-cv-00812. The complaint alleged that prior to our August 10, 2020 receipt of a Complete Response Letter from the FDA

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concerning our NDA for PEDMARK, defendants made materially false or misleading statements and failed to disclose material facts about our third-party PEDMARK product manufacturing facility and the impact the facility would have on regulatory approval for PEDMARK. On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our Board of Directors as defendants, asserts a putative class period from December 20, 2018 through August 10, 2020, makes allegations similar to those in the original complaint, claims the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, and seeks an unspecified amount of compensatory damages and attorneys' fees and costs.

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

On March 30, 2022, lead plaintiff filed a motion for post judgment relief, seeking leave to file a second amended complaint. In his proposed second amended complaint, lead plaintiff seeks to add allegations stemming from the receipt of a second CRL following our resubmission of our NDA for PEDMARK, which we received on November 29, 2021, among other things. Defendants filed an opposition to plaintiff's motion for post judgment relief on April 20, 2022. On May 4, 2022, lead plaintiff submitted a reply in support of his motion. On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it has approved PEDMARK. On October 18, 2022, lead plaintiff filed his opposition to request for judicial notice. On October 21, 2022, defendants filed a reply in support of the request for judicial notice.

We believe that this lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of September 30, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Fisher v. Fennec Pharmaceuticals Inc. et al.

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

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

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On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it approved PEDMARK. On September 30, 2022, lead plaintiff filed an opposition to the request for judicial notice. On October 6, 2022, defendants filed a reply in support of the request for judicial notice. On October 12, 2022, the U.S. District Court Judge issued a memorandum opinion and order dismissing the amended complaint in its entirety and with prejudice, and on October 14, 2022, entered judgment. Lead plaintiff has until November 14, 2022 to file a notice of appeal.

We believe that the lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of September 30, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Hope Medical Enterprises, Inc.

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed two petitions for inter partes review ("IPR") with the Patent Trial and Appeal Board ("PTAB") of the USPTO. In its petitions, Hope seeks to invalidate our U.S. Patent No. 10,596,190 ("US '190"), which is exclusively in-licensed from OHSU and relates to a method of using our PEDMARK product, and our U.S. Patent No. 10,792,363 ("US '363"), which relates to an anhydrous form of STS, which is the active pharmaceutical ingredient in our PEDMARK product. US '190 was issued on March 24, 2020. US '363 was issued on October 6, 2020.

On January 11, 2022, OHSU filed a Request for Supplemental Examination of US '190 requesting the consideration by the Central Re-examination Unit ("CRU") of the USPTO of certain prior art references, including references cited by Hope in its Petition for IPR that are relevant to the granted claim of the patent. On May 9, the PTAB granted Hope Medical's Petition to Institute the IPR against the '190 patent and a stayed the Supplemental Examination pending the result of the '190 IPR. On August 12, 2022, we filed a Motion to Amend the single claim of the '190 Patent in the IPR to focus on the treatment of medulloblastoma. We expect a decision in the '190 IPR in May 2023, which can be appealed by the losing party. Further, in May 2022, the PTAB granted Hope Medical's Petition to Institute the IPR against the '363 patent. During the '363 IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. We expect a decision in the '363 IPR in May 2023, which can be appealed by the losing party.

On April 5, 2022, the USPTO issued U.S. Patent No. 11,291,728 ('728) that covers the PEDMARK pharmaceutical formulation. On September 14, 2022, the USPTO issued Notices of Allowance to us for two additional patent applications that cover the PEDMARK pharmaceutical formulation. We expect these two additional U.S. patents to issue in Q4 of 2022 or Q1 of 2023. These patents will expire in 2039, unless held invalid or unenforceable by a court of final jurisdiction.

On approval of PEDMARK, we listed the '728 and the '190 patents in the FDA Orange Book. We plan to update the Orange Book with additional patents granted by the USPTO on issuance. We obtained U.S. Orphan Drug Designation for the use of PEDMARK in the prevention of platinum-induced ototoxicity in pediatric patients in 2004. We plan to pursue PUMA upon approval of the MAA, which would allow for 10 years of market exclusivity upon PUMA approval.

We plan to vigorously defend our intellectual property rights related to PEDMARK. However, we are unable to predict the outcome of Hope's IPR petitions, or the Supplemental Examination. While we now have, or will shortly receive, additional U.S. patents that cover PEDMARK over the IPR challenged patents, an invalidation of our patents covering PEDMARK could have a material adverse effect on our ability to protect our rights in PEDMARK beyond periods of marketing exclusivity for PEDMARK possible in the United States under Orphan Drug Designation and in Europe under European Market Exclusivity for Pediatric Use ("PUMA").

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Executive Severance

In the event of his termination with us other than for cause, we will be obligated to pay Mr. Raykov a one-time severance payment equal to twelve months of salary (\$513 as of September 30, 2022). In the event of his termination with us other than for cause, we will be obligated to pay Mr. Andrade a one-time severance payment equal to six months of salary (\$186 as of September 30, 2022).

Leases

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

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

COVID-19

Our operations may be affected by the ongoing COVID-19 pandemic. The ultimate disruption that may be caused by the outbreak is uncertain; however, it may result in a material adverse impact on our financial position, operations and cash flows. Possible effects may include, but are not limited to, disruption to our product launch which includes the ability of sales reps to communicate with oncologists, absenteeism in our labor workforce, unavailability of products and supplies used in operations, and a decline in value of our assets, including inventories, property and equipment, and marketable securities. COVID-19 has not had a material effect on our operations to date as we have historically had a workforce which works remotely, preparations for product launch have been under the assumption of a virtual launch, and product supplies have not been impacted.

7. Term Loans

On August 1, 2022, the Company entered into the SPA with the Creditor 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 note becomes due on the maturity date, which is August 19, 2027.

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

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

A commitment fee of 2.0% of the Notes is payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 of the Company's common shares and half was payable in cash or warrants of 55,498 of the Company's common shares, at our election, on the second closing. The Company chose to issue warrants to

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satisfy the payable on second closing. The warrants will be exercisable at a price per share of \$8.11 and will have a term of five years from the date of the grant. The maturity date of the second tranche is September 23, 2027.

Cash interest on outstanding principal shall accrue at a rate of prime, plus 4.5% per annum (10.75% as of September 30, 2022), from the date of funding. Cash interest is due on the first business day of each calendar quarter ("Interest Date"). Payment-in-kind ("PIK") interest will commence on funding date and accrue at a rate of 3.5% per annum (9.75% as of September 30, 2022). PIK interest will stop accruing on August 24, 2024. Any accrued PIK interest shall remain outstanding and be payable on each Interest Date and be added to the outstanding principal amount.

The 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.

Aggregate annual payments due on the SPA as of September 30, 2022, are as follows:

Years Ending December 31,	Amount
2022	\$ —
2023	—
2024	—
2025	—
2026	—
2027	25,000
Total future payments	25,000
Less: unamortized debt discount	(312)
Total term loan, net of debt discount	\$ 24,688

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

Debt issuance costs amounting to \$175 were paid in cash to the Creditor and warrants valued at \$441 (non-cash) secured 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 term of the SPA.

8. Subsequent Events

On October 17, 2022, the Company announced the U.S. commercial launch and availability of PEDMARK[®] for pediatric patients one month of age and older.

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

CAUTIONARY STATEMENT

This section and other parts of this Quarterly Report on Form 10-Q contain 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. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021 under the heading “Risk Factors.” We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2021 and the condensed consolidated financial statements and accompanying notes included elsewhere in this report.

Overview

We are a commercial-stage biopharmaceutical company focused on our only product PEDMARK[®]. On September 20, 2022 we received approval from the FDA for PEDMARK[®] (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. This approval makes PEDMARK[®] the first and only treatment approved by the FDA in this area of significant unmet medical need. On October 17, 2022 we announced commercial availability of PEDMARK[®] in the United States.

We sell our product through an experienced field force including Regional Pediatric Oncology Specialists and medical science liaisons who are helping to educate the medical communities and patients about cisplatin induced ototoxicity and our programs supporting patient access to PEDMARK[®].

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

We currently have two patents listed for PEDMARK[®] in the FDA's Orange Book. In March 2020, the United States Patent and Trademark Office, or USPTO, allowed Patent No. 10,596,190 (“US ‘190”), which is exclusively in-licensed from Oregon Health & Science University (“OHSU”) and relates to a method of using our PEDMARK[®] product. In September 2022, the USPTO issued Patent No. 11,291,728 (“728”) which is a formulation patent. The “190” and “728” patents will expire in 2038 and 2039, respectively, unless held invalid or unenforceable by a court or final jurisdiction. Further, on September 14, 2022, the USPTO issued Notices of Allowance to us for two additional patent applications that cover the PEDMARK[®] pharmaceutical formulation. We expect these two additional U.S. patents to issue in Q4 of 2022 or Q1 of 2023. These patents will expire in 2039, unless held invalid or unenforceable by a court of final jurisdiction. We are also pursuing additional patent applications in both the U.S. and internationally for PEDMARK[®].

Hearing loss among children receiving platinum-based chemotherapy is frequent, permanent and often severely disabling. The incidence of hearing loss in these children depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. In addition, adults undergoing chemotherapy for several common malignancies, including ovarian cancer, testicular cancer, and particularly head and neck cancer and brain cancer, often receive intensive platinum-based therapy and may experience severe, irreversible hearing loss, particularly in the high frequencies.

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

In August 2018, the Pediatric Committee (“PDCO”) of the European Medicines Agency (“EMA”) accepted our pediatric investigation plan (“PIP”) for sodium thiosulfate with the trade name Pedmarqsi for the condition of the prevention of platinum-induced hearing loss. An accepted PIP is a prerequisite for filing a Marketing Authorization Application (“MAA”) for any new medicinal product in Europe. The indication targeted by our PIP is for the prevention of platinum-induced ototoxic hearing loss for standard risk hepatoblastoma (“SR-HB”). Additional tumor types of the proposed indication will be subject to the Committee for Medicinal Products for Human Use (“CHMP”) assessment at the time of the MAA. No deferred clinical studies were required in the positive opinion given by PDCO. We were also advised that sodium thiosulfate (tradenname to be determined) is eligible for submission of an application for a Pediatric Use Marketing Authorization (“PUMA”). A PUMA is a dedicated marketing authorization covering the indication and appropriate formulation for medicines developed exclusively for use in the pediatric population and provides data and market protection up to 10 years. Therefore, this decision allows us to proceed with the submission of a PUMA in the European Union (“EU”) with incentives of automatic access to the centralized procedure and up to 10 years of data and market protection. In February 2020, we announced that we had submitted a MAA for the prevention of ototoxicity induced by cisplatin chemotherapy patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. The EMA continues its review of our MAA.

Capital Funding

We have not received revenues from the sale of PEDMARK[®] as of September 30, 2022. Now that we have obtained applicable regulatory approval to sell PEDMARK[®], we recognize there may still be a need to establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue.

We generated a net loss of approximately \$16.9 million for the nine months ended September 30, 2022, and a net loss of \$12.9 million for the nine months ended September 30, 2021. As of September 30, 2022, our accumulated deficit was approximately \$196.3 million (\$179.5 million at December 31, 2021).

We believe that our cash and cash equivalents as of September 30, 2022, which totaled \$29.8 million, plus the remaining available Petrichor Financing of \$20 million in convertible notes (see Note 1 and Note 7 to condensed consolidated financial statements contained elsewhere in this report), will be sufficient to meet our cash requirements through at least the next twelve months, including commercial launch of PEDMARK[®] in the United States. Our projections of our capital requirements are subject to substantial uncertainty, and more capital than we currently anticipate may be required thereafter. To finance our continuing operations, we may need to raise substantial additional funds through either the sale of additional equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out-license or sale of certain aspects of our intellectual property portfolio or from other sources. We may not be able to raise the necessary capital, or such funding may not be available on financially acceptable terms if at all. If we cannot obtain adequate funding in the future, we might be required to further delay, scale back or eliminate certain research and development studies, consider business combinations, or even shut down some, or all, of our operations.

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

Results of Operations

Three months ended September 30, 2022 versus three months ended September 30, 2021:

In thousands of U.S. Dollars	Three Months Ended September 30, 2022	%	Three Months Ended September 30, 2021	%	Change
Revenue	\$ —		\$ —		\$ —
Operating expenses:					
Research and development	846	11 %	1,242	30 %	(396)
General and administration	7,053	89 %	2,931	70 %	4,122
Total operating expense	7,899	100 %	4,173	100 %	3,726
Loss from operations	(7,899)		(4,173)		(3,726)
Unrealized (loss)/gain on securities	(27)		39		(66)
Foreign currency transaction loss	(4)		(1)		(3)
Amortization expense	(64)		(8)		(56)
Interest expense	(119)		(55)		(64)
Interest income	24		13		11
Net loss	<u>\$ (8,089)</u>		<u>\$ (4,185)</u>		<u>\$ (3,904)</u>

Research and development expenses decreased by \$396 for the three months ended September 30, 2022, compared to the same period in 2021. The Company's research and development activities during three months ended September 30, 2022 decreased as the Company's efforts on a year over year basis were more focused on commercial readiness for the launch of PEDMARK rather than development and regulatory activities. General and administrative expenses increased by \$4,122 over same period in 2021. There was an increase in non-cash equity compensation of \$970 for the three months ended September 30, 2022, over the same period in 2021. This increase is attributable to grants to new employees and the expense associated with equity awards which vested upon FDA approval of PEDMARK[®]. Salaries and wage expense increased by \$1,212 for the three months ended September 30, 2022 over the same period in 2021. This increase was a result of increased headcount primarily related to the commercial team. Legal expenses increased \$341 over same period in the prior year primarily as a result of the class action suits and patent defense. Sales and marketing activities increased by \$620 over the same period in prior year as commercialization readiness activities increased.

The Company holds shares of Procesa (NASDAQ: PCSA) which are marked to market each balance sheet date and unrealized gains or losses are recognized at that time. The unrealized loss on those shares for the three months ended September 30, 2022 was \$27. The Company has vendors that transact in Euros, Great British Pounds and Canadian Dollars. There was a foreign currency transaction loss of \$4 for the three months ended September 30, 2022, compared to a \$1 loss for the same period in 2021. Amortization expense is a non-cash expense and relates to amortization of the deferred issuance cost of the loan facilities with Bridge Bank and Petrichor. Amortization expense increased by \$56 for the three months ended September 30, 2022, compared to the same period in 2021. Interest expense increased by \$64 for the three months ended September 30, 2022, over the same period in 2021. The increase relates to the interest being paid on the Bridge Bank loan facility and the Petrichor notes. Interest income was \$11 higher for the three months ended September 30, 2022, compared to the same period in 2021. This was driven mainly by higher average cash balances and higher interest rates, for the three months ended September 30, 2022 compared to the same period in 2021.

Nine months ended September 30, 2022 versus nine months ended September 30, 2021:

In thousands of U.S. Dollars	Nine Months Ended September 30, 2022	%	Nine Months Ended September 30, 2021	%	Change
Revenue	\$ —		\$ —		\$ —
Operating expenses:					
Research and development	3,414	21 %	4,458	34 %	(1,044)
General and administration	13,040	79 %	8,558	66 %	4,482
Total operating expenses	16,454	100 %	13,016	100 %	3,438
Loss from operations	(16,454)		(13,016)		(3,438)
Unrealized (loss)/gain on securities	(126)		137		(263)
Foreign currency transaction gain/(loss)	(6)		(9)		3
Amortization expense	(79)		(8)		(71)
Interest expense	(234)		(64)		(170)
Interest income	42		41		1
Net loss	\$ (16,857)		\$ (12,919)		\$ (3,938)

Research and development expenses decreased by \$1,044 for the nine months ended September 30, 2022, compared to the same period in 2021. The main drivers of this decrease were a decline in manufacturing activities and regulatory expenses. General and administrative expenses increased by \$4,482 over the same period in 2021 primarily related to legal expenses, non-cash equity compensation and higher wages from increased headcount.

The Company holds shares of Proccessa (NASDAQ: PCSA) which are marked to market each balance sheet date and unrealized gains or losses are recognized at that time. The unrealized loss on those shares for the nine months ended on September 30, 2022 was \$126, which is in contrast to the \$137 gain for the same period in 2021. Foreign currency transaction loss was \$6 for the nine months ended September 30, 2022 (\$9 loss for same period in 2021). Amortization expense was \$79 for the nine months ended September 30, 2022 compared to \$8 for the same period in 2021. In 2022, the Company wrote off the remaining unamortized balance associated with the Bridge Bank facility after it was paid off. At the same time, the Company started to amortize the debt issuance costs associated with the Petrichor notes. Interest expense increased \$170 for the nine months ended September 30, 2022 over same period in 2021. The expense relates to interest on the Bridge Bank loan facility and the Petrichor convertible notes. Interest income was \$1 higher for the nine months ended September 30, 2022, compared to the same period in 2021. This was driven mainly by higher interest rates for the nine months ended September 30, 2022 compared to the same period in 2021.

Liquidity and Capital Resources

Selected Asset and Liability Data (thousands):	As of September 30, 2022	As of December 31, 2021
Cash and equivalents	\$ 29,752	\$ 21,100
Other current assets	401	1,287
Current liabilities	2,927	1,654
Working capital ⁽¹⁾	27,226	20,733
⁽¹⁾ [Current assets – current liabilities]		

Selected Equity:

Common stock and additional paid in capital	197,902	194,015
Accumulated deficit	(196,343)	(179,486)
Shareholders' equity	2,802	15,772

Cash and cash equivalents were \$29,752 at September 30, 2022 and \$21,100 at December 31, 2021. The increase in cash and cash equivalents between September 30, 2022 and December 31, 2021 is the result of expenses related to the development and preparation of the NDA resubmission of PEDMARK[®] and general and administrative expenses, which

was offset by inflows from the Petrichor notes and modest cash inflows of \$249 from various option exercises. There was a decrease of \$886 in other current assets between September 30, 2022 and December 31, 2021.

Current liabilities increased by \$1,273 between September 30, 2022 and December 31, 2021. The increase was driven mainly by increased expenses as we neared the anticipated PEDMARK[®] commercialization.

Working capital increased between December 31, 2021 and September 30, 2022 by \$6,493. The increase relates to a net cash inflow from the Petrichor notes and various option exercises, offset by expenditures for operating activities for the nine months ended September 30, 2022. The Company expects increases in cash outflows related to commercialization activities in the coming quarters as the Company expands its commercialization efforts related to PEDMARK[®].

The following table illustrates a summary of cash flow data for the three and nine month periods ended September 30, 2022 and 2021:

Selected Cash Flow Data (dollars in thousands)	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	\$ (11,256)	\$ (10,977)
Net cash provided by investing activities	—	—
Net cash provided by financing activities	19,908	4,968
Net cash flow	<u>\$ 8,652</u>	<u>\$ (6,009)</u>

Net cash used in operating activities for the nine months ended September 30, 2022 primarily reflected a net loss of \$16,857. The nine month losses were adjusted for the add back of non-cash items consisting of \$3,363 in stock-based compensation expense, amortization expense of \$79, and unrealized loss on securities of \$126 added back for the nine months ended September 30, 2022. For the nine months ended September 30, 2022, there was a net change in prepaid and other assets of \$756, coupled with a net increase in current liabilities of \$1,273. Nine month cash flows from operating activities were negative \$11,256 for the period ended September 30, 2022. Net cash provided by financing activities for the nine months ended September 30, 2022, was \$19,908. Financing activities consisted of proceeds from the Petrichor notes, net of capitalized costs, cash paid for taxes on restricted share releases and exercises of various options. Net cash flows from the nine month period ended September 30, 2022 were \$8,652.

We continue to pursue various strategic alternatives including potential 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: sales volume of our product, our ability to obtain additional financial resources; our ability to enter into collaborations that provide us with up-front payments, milestones or other payments; results of our research and development activities; 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 potential expanded commercialization activities.

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, 2022, we had approximately \$438 in our cash accounts and \$29,314 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. As our main purpose is preservation of capital while we endeavor to become cash flow positive through the sale of our product, we have chosen to avoid investments of a trading or speculative nature.

Since our inception, we have not had any material off-balance sheet arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such activities.

Research and Development

Our research and development efforts have been focused on the development of PEDMARK since 2013.

We have established relationships with contract research organizations, universities and other institutions, which we utilize to perform many of the day-to-day activities associated with our drug development. Where possible, we have sought to include leading scientific investigators and advisors to enhance our internal capabilities. Research and development issues are reviewed internally by our executive management and supporting scientific team.

Research and development expenses for the three and nine months ended September 30, 2022 was \$846 and \$3,414, respectively. For the same periods in 2021, research and development expense was \$1,242 and \$4,458, respectively. We have decreased our research and development expenses related to PEDMARK® as our efforts have shifted to commercial readiness activities.

PEDMARK® still requires significant, time-consuming and costly research and development, testing and regulatory clearances. In developing PEDMARK®, we are subject to risks of failure that are inherent in the development of products based on innovative technologies. For example, it is possible that our product candidate will be ineffective or toxic, or will otherwise fail to receive the necessary regulatory clearances. There is a risk that PEDMARK® will be uneconomical to manufacture or market or will not achieve market acceptance. There is also a risk that third parties may hold proprietary rights that preclude us from marketing our product candidate or that others will market a superior or equivalent product. As a result of these factors, we are unable to accurately estimate the nature, timing and future costs necessary to complete the development of this product candidate. In addition, we are unable to reasonably estimate the period when material net cash inflows could commence from the sale, licensing or commercialization of such product candidate, if ever.

Critical Accounting Policies and Use of 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 on Form 10-K for the fiscal year ended December 31, 2021 (filed February 28, 2022). There have been no material changes to our critical accounting policies and use of estimates during the nine months ended September 30, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Money Market Investments

We maintain an investment portfolio consisting of U.S. or Canadian obligations and bank securities and money market investments in compliance with our investment 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 a maximum-weighted average time to maturity of twelve months. This policy applies to all of our financial resources.

At September 30, 2022, we had \$29,314 in money market investments and savings accounts as compared to \$21,018 at December 31, 2021; these investments typically have minimal risk. 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.

Variable Interest Rate Risk

We are subject to interest rate fluctuation exposure through our borrowings under the SPA and our investment in money market accounts, both of which bear a variable interest rate. Borrowings under the SPA bear an interest rate of prime plus 4.5%. Payment-in-kind interest is also variable and accrues at a rate of prime plus 3.5%. Increases in interest rates may adversely affect our ability to meet our obligations.

Foreign Currency Exposure

We are subject to foreign currency risks as we purchase goods and services which are denominated in Euro, Great British Pounds and Canadian dollars. To date, we have not employed the use of derivative instruments; however, we do hold Canadian dollars which we use to pay vendors in Canada and other corporate obligations. At September 30, 2022, we held approximately \$45 Canadian dollars (\$33 as presented to U.S. dollars). At December 31, 2021, we held approximately \$43 Canadian dollars (\$34 as presented into U.S. dollars).

Item 4. Controls and Procedures.

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

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Based on this evaluation at the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and our Chief Financial Officer, have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

(b) *Changes in Internal Control over Financial Reporting*

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

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

Chapman v. Fennec Pharmaceuticals Inc. et al.

On September 3, 2020, plaintiff Jim Chapman filed a putative federal securities class action lawsuit against the Company, our Chief Executive Officer, Rostislav Raykov, and Chief Financial Officer, Robert Andrade, in the United States District Court for the Middle District of North Carolina, captioned *Chapman v. Fennec Pharmaceuticals Inc. et al.*, Case No. 1:20-cv-00812. The complaint alleged that prior to our August 10, 2020 receipt of a CRL from the FDA concerning our NDA for PEDMARK[®], defendants made materially false or misleading statements and failed to disclose material facts about

our third-party PEDMARK[®] product manufacturing facility and the impact the facility would have on regulatory approval for PEDMARK[®]. On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our Board of Directors as defendants, asserts a putative class period from December 20, 2018 through August 10, 2020, makes allegations similar to those in the original complaint, claims the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, and seeks an unspecified amount of compensatory damages and attorneys' fees and costs.

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

On March 30, 2022, lead plaintiff filed a motion for post judgment relief, seeking leave to file a second amended complaint. In his proposed second amended complaint, lead plaintiff seeks to add allegations stemming from the receipt of a second CRL following our resubmission of our NDA for PEDMARK[®], which we received on November 29, 2021, among other things. Defendants filed an opposition to plaintiff's motion for post judgment relief on April 20, 2022. On May 4, 2022, lead plaintiff submitted a reply in support of his motion. On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it has approved PEDMARK[®]. On October 18, 2022, lead plaintiff filed his opposition to request for judicial notice. On October 21, 2022, defendants filed a reply in support of the request for judicial notice.

We believe that this lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of September 30, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Fisher v. Fennec Pharmaceuticals Inc. et al.

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

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

On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it approved PEDMARK[®]. On September 30, 2022, lead plaintiff filed an opposition to the request for judicial notice. On October 6, 2022, defendants filed a reply in support of the request for judicial notice. On October 12, 2022, the U.S. District Court Judge issued a memorandum opinion and order dismissing the amended complaint in its entirety and with

prejudice, and on October 14, 2022, entered judgment. Lead plaintiff has until November 14, 2022 to file a notice of appeal.

We believe that the lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of September 30, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Hope Medical Enterprises, Inc.

On October 29, 2021, Hope Medical Enterprises, Inc. (“Hope”) filed two petitions for inter partes review (“IPR”) with the Patent Trial and Appeal Board (“PTAB”) of the USPTO. In its petitions, Hope seeks to invalidate our U.S. Patent No. 10,596,190 (“US ‘190”), which is exclusively in-licensed from OHSU and relates to a method of using our PEDMARK® product, and our U.S. Patent No. 10,792,363 (“US ‘363”), which relates to an anhydrous form of STS, which is the active pharmaceutical ingredient in our PEDMARK® product. US ‘190 was issued on March 24, 2020. US ‘363 was issued on October 6, 2020.

On January 11, 2022, OHSU filed a Request for Supplemental Examination of US ‘190 requesting the consideration by the Central Re-examination Unit (“CRU”) of the USPTO of certain prior art references, including references cited by Hope in its Petition for IPR that are relevant to the granted claim of the patent. On May 9, the PTAB granted Hope Medical’s Petition to Institute the IPR against the ‘190 patent and a stayed the Supplemental Examination pending the result of the ‘190 IPR. On August 12, 2022, we filed a Motion to Amend the single claim of the ‘190 Patent in the IPR to focus on the treatment of medulloblastoma. We expect a decision in the ‘190 IPR in May 2023, which can be appealed by the losing party. Further, in May 2022, the PTAB granted Hope Medical’s Petition to Institute the IPR against the ‘363 patent. During the ‘363 IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. We expect a decision in the ‘363 IPR in May 2023, which can be appealed by the losing party.

On April 5, 2022, the USPTO issued U.S. Patent No. 11,291,728 (‘728) that covers the PEDMARK pharmaceutical formulation. On September 14, 2022, the USPTO issued Notices of Allowance to us for two additional patent applications that cover the PEDMARK pharmaceutical formulation. We expect these two additional U.S. patents to issue in Q4 of 2022 or Q1 of 2023. These patents will expire in 2039, unless held invalid or unenforceable by a court of final jurisdiction.

On approval of PEDMARK, we listed the ‘728 and the ‘190 patents in the FDA Orange Book. We plan to update the Orange Book with additional patents granted by the USPTO on issuance. We obtained U.S. Orphan Drug Designation for the use of PEDMARK in the prevention of platinum-induced ototoxicity in pediatric patients in 2004. We plan to pursue PUMA upon approval of the MAA, which would allow for 10 years of market exclusivity upon PUMA approval.

We plan to vigorously defend our intellectual property rights related to PEDMARK. However, we are unable to predict the outcome of Hope’s IPR petitions, or the Supplemental Examination. While we now have, or will shortly receive, additional U.S. patents that cover PEDMARK™ over the IPR challenged patents, an invalidation of our patents covering PEDMARK could have a material adverse effect on our ability to protect our rights in PEDMARK beyond periods of marketing exclusivity for PEDMARK possible in the United States under Orphan Drug Designation and in Europe under European Market Exclusivity for Pediatric Use (“PUMA”).

Item 1A. Risk Factors.

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 28, 2022 (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.

On November 11, 2022, we issued a press release announcing our financial results for the quarter ended September 30, 2022. A copy of the news release is attached to this report as Exhibit 99.1. The press release is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references the press release.

Item 6. Exhibits

Exhibit No.	Description
31.1	Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
99.1	Press Release for Quarter Ended September 30, 2022 (filed herewith).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

SIGNATURES

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

Fennec Pharmaceuticals Inc.

Date: November 14, 2022

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

Date: November 14, 2022

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

**FENNEC PHARMACEUTICALS INC
CERTIFICATION**

I, Rostislav Raykov, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2022 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 14, 2022

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

**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, 2022 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 14, 2022

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

**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, 2022 (the "Report"), each of the undersigned, Rostislav Raykov, Chief Executive Officer of the Company, and Robert Andrade, Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 14, 2022

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

Date: November 14, 2022

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



FENNEC PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ In September 2022, FDA Approved PEDMARK[®], the First and Only FDA-Approved Therapy Indicated to Reduce the Risk of Ototoxicity Associated with Cisplatin in Pediatric Patients with Localized, Non-Metastatic Tumors ~

~ Initiated U.S. Commercial Launch of PEDMARK[®] in October 2022 ~

~ Closed \$25 Million in Funding from Petrichor to Support the U.S. Commercialization of PEDMARK[®], With the Potential to Access an Additional \$20 Million Prior to December 31, 2023 ~

Research Triangle Park, NC, November 11, 2022 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a commercial stage specialty pharmaceutical company focused on the development of PEDMARK[®] (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors today reported its financial results for the fiscal quarter ended September 30, 2022 and provided a business update.

“This was an important quarter for Fennec with the FDA approval of PEDMARK[®] and the successful buildout of our commercial infrastructure leading to the recent U.S. commercial launch of PEDMARK. In addition, we successfully completed a \$25 million financing, which we believe well positions the Company for the launch of PEDMARK,” said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. “PEDMARK provides the first and only FDA-approved treatment specifically designed to help protect hearing in children and young adults after receiving cisplatin. We remain focused on continuing our engagement with healthcare providers and supporting pediatric patient access to this breakthrough therapy.”

Financial Results for the Third Quarter 2022

- **Cash Position** – Cash and cash equivalents were \$29.8 million at September 30, 2022. The increase in cash and cash equivalents between September 30, 2022, and December 31, 2021, is the result of cash inflow from the Petrichor financing offset by cash paid to Bridge Bank to pay off Loan Security Agreement, and expenditures related to the commercial readiness activities for PEDMARK[®] and general and administrative expenses.
- **Research and Development (R&D) Expenses** – R&D expenses decreased by \$0.4 million for the three months ended September 30, 2022, compared to the same period in 2021. The Company’s research and development activities during the quarter decreased as the Company’s efforts on a year-over-year basis were more focused on commercial readiness.
- **General and Administrative (G&A) Expenses** – General and administrative expenses increased by \$4.1 million over same period in 2021. The increase in general and administrative expenses over the same period in 2021 reflects increased expenses related to commercial readiness activities, including increased headcount, non-cash equity compensation for employees and increased legal expenses.
- **Net Loss** – Net loss for the three months ended September 30, 2022 was \$8.1 million (\$0.31 per share), compared to \$4.1 million (\$0.16 per share) for the same period in 2021.

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, 2022 and management's discussion and analysis of

financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

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

	Three Months Ended	
	September 30, 2022	September 30, 2021
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	846	1,242
General and administrative	7,053	2,931
Total operating expenses	<u>7,899</u>	<u>4,173</u>
Loss from operations	<u>(7,899)</u>	<u>(4,173)</u>
Other (expense)/income		
Foreign currency transaction (loss)/gain	(4)	(1)
Amortization expense	(64)	(8)
Unrealized (loss)/gain on securities	(27)	39
Interest income	24	13
Interest expense	(119)	(55)
Total other (expense)/income	<u>(190)</u>	<u>(12)</u>
Net loss	<u>\$ (8,089)</u>	<u>\$ (4,185)</u>
Basic net loss per common share	<u>\$ (0.31)</u>	<u>\$ (0.16)</u>
Diluted net loss per common share	<u>\$ (0.31)</u>	<u>\$ (0.16)</u>
Weighted-average number of common shares outstanding basic	<u>26,108</u>	<u>26,007</u>
Weighted-average number of common shares outstanding diluted	<u>26,108</u>	<u>26,007</u>

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

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 29,752	\$ 21,100
Prepaid expenses	278	1,034
Other current assets	123	253
Total current assets	<u>30,153</u>	<u>22,387</u>
Non-current assets		
Deferred issuance cost, net of amortization	264	27
Total non-current assets	<u>264</u>	<u>27</u>
Total assets	<u>\$ 30,417</u>	<u>\$ 22,414</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,533	\$ 777
Accrued liabilities	394	877
Total current liabilities	<u>2,927</u>	<u>1,654</u>
Long-term liabilities		
Term loan	25,000	5,000
Debt discount	(312)	(12)
Total long-term liabilities	<u>24,688</u>	<u>4,988</u>
Total liabilities	<u>27,615</u>	<u>6,642</u>
Stockholders' equity:		
Common stock, no par value; unlimited shares authorized; 26,238 shares issued and outstanding (2021 - 26,014)	141,309	140,801
Additional paid-in capital	56,593	53,214
Accumulated deficit	(196,343)	(179,486)
Accumulated other comprehensive income	1,243	1,243
Total stockholders' equity	<u>2,802</u>	<u>15,772</u>
Total liabilities and stockholders' equity	<u>\$ 30,417</u>	<u>\$ 22,414</u>

Selected Asset and Liability Data (thousands):	As of September 30, 2022	As of December 31, 2021
Cash and equivalents	\$ 29,752	\$ 21,100
Other current assets	401	1,287
Current liabilities	2,927	1,654
Working capital (1)	\$ 27,226	\$ 20,733
(1) [Current assets – current liabilities]		

Selected Equity:		
Common stock and additional paid in capital	197,902	194,015
Accumulated deficit	(196,343)	(179,486)
Shareholders' equity	2,802	15,772

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and has received Orphan Drug Designation in the U.S. Fennec has a license agreement with Oregon Health and Science University (OHSU) for exclusive worldwide license rights to intellectual property directed to sodium thiosulfate and its use for chemoprotection, including the reduction of risk of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com.

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline, and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company’s business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company’s patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company’s products will not be as large as expected, the Company’s products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company’s filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2021. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

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

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