

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, 2020

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  
Yes  No

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

Large Accelerated Filer  Accelerated Filer   
Non-Accelerated Filer  Smaller reporting company   
Emerging growth company

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

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

As of November 11, 2020, there were 25,809,684 shares of Fennec Pharmaceuticals Inc. common stock outstanding.

## TABLE OF CONTENTS

	<b>Page</b>
<b><u>PART I: FINANCIAL INFORMATION</u></b>	<b><u>3</u></b>
<u>Item 1. Condensed Consolidated Financial Statements</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of September 30, 2020 (Unaudited) and December 31, 2019</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine-months Ended September 30, 2020 and 2019</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three and Nine-months Ended September 30, 2020 and 2019</u>	<u>5</u>
<u>Condensed Consolidated Statements of Stockholders' Equity (Unaudited) for the Three and Nine-months Ended September 30, 2020 and 2019</u>	<u>6</u>
<u>Notes to the Condensed Consolidated Financial Statements</u>	<u>7</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</u>
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	<u>25</u>
<u>Item 4. Controls and Procedures</u>	<u>25</u>
<b><u>PART II: OTHER INFORMATION</u></b>	<b><u>26</u></b>
<u>Item 1. Legal Proceedings</u>	<u>26</u>
<u>Item 1A. Risk Factors</u>	<u>26</u>
<u>Item 2. Recent Sales of Unregistered Securities</u>	<u>29</u>
<u>Item 3. Default Upon Senior Securities</u>	<u>29</u>
<u>Item 4. Mine Safety Disclosure</u>	<u>29</u>
<u>Item 5. Other Information</u>	<u>29</u>
<u>Item 6. Exhibits</u>	<u>30</u>
<u>Signatures</u>	<u>31</u>

**PART 1: FINANCIAL INFORMATION**  
**Item 1. Financial Statements**

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

	September 30, 2020 (unaudited)	December 31, 2019
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 33,166	\$ 13,650
Prepaid expenses	900	226
Other current assets	4	8
<b>Total current assets</b>	<u>34,070</u>	<u>13,884</u>
<b>Non-current assets:</b>		
Deferred issuance costs	466	326
Accumulated amortization of deferred issuance costs	(466)	(64)
<b>Total non-current assets:</b>	<u>-</u>	<u>262</u>
<b>Total assets</b>	<u>\$ 34,070</u>	<u>\$ 14,146</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,684	\$ 1,612
Accrued liabilities	201	659
<b>Total current liabilities</b>	<u>2,885</u>	<u>2,271</u>
<b>Commitments and Contingencies (Note 6)</b>		
<b>Stockholders' equity:</b>		
Common stock, no par value; unlimited shares authorized; 25,810 shares issued and outstanding (2019-19,896)	139,732	106,392
Additional paid-in capital	49,112	48,271
Accumulated deficit	(158,902)	(144,031)
Accumulated other comprehensive income	1,243	1,243
<b>Total stockholders' equity</b>	<u>31,185</u>	<u>11,875</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 34,070</u>	<u>\$ 14,146</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)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2020</b>	<b>September 30, 2019</b>	<b>September 30, 2020</b>	<b>September 30, 2019</b>
<b>Revenue</b>	\$ -	\$ -	\$ -	\$ -
<b>Operating expenses:</b>				
Research and development	1,368	795	3,882	4,435
General and administrative	4,491	1,068	10,657	4,921
<b>Loss from operations</b>	<u>(5,859)</u>	<u>(1,863)</u>	<u>(14,539)</u>	<u>(9,356)</u>
<b>Other (expense) income :</b>				
Other (loss)/gain	(8)	1	(4)	(9)
Amortization expense	(355)	(17)	(402)	(46)
Interest income and other	22	70	74	246
Total other income/(expense), net	<u>(341)</u>	<u>54</u>	<u>(332)</u>	<u>191</u>
<b>Net loss</b>	<u>\$ (6,200)</u>	<u>\$ (1,809)</u>	<u>\$ (14,871)</u>	<u>\$ (9,165)</u>
<b>Basic net loss per common share</b>	\$ (0.24)	\$ (0.09)	\$ (0.64)	\$ (0.46)
<b>Diluted net loss per common share</b>	\$ (0.24)	\$ (0.09)	\$ (0.64)	\$ (0.46)
<b>Weighted-average number of common shares outstanding, basic</b>	25,598	19,896	22,969	19,896
<b>Weighted-average number of common shares outstanding, diluted</b>	25,598	19,896	22,969	19,896

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

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2020</b>	<b>September 30, 2019</b>	<b>September 30, 2020</b>	<b>September 30, 2019</b>
<b>Cash flows used in:</b>				
<b>Operating activities:</b>				
Net loss	\$ (6,200)	\$ (1,809)	\$ (14,871)	\$ (9,165)
Adjustments to reconcile net loss to net cash used in operating activities:				
Amortization of deferred issuance cost	355	17	402	46
Stock-based compensation - contractors	21	21	63	395
Stock-based compensation - employees	1,238	314	2,151	2,204
Changes in operating assets and liabilities:				
Prepaid assets	(734)	(331)	(674)	(219)
Other current assets	-	1	4	1
Accounts payable	(71)	(440)	1,072	(244)
Accrued liabilities	(55)	(8)	(458)	(488)
Net cash used in operating activities	<u>(5,446)</u>	<u>(2,235)</u>	<u>(12,311)</u>	<u>(7,470)</u>
<b>Financing activities:</b>				
Issuance of shares, net of issuance cost	-	-	31,967	-
Capitalized deferred issuance cost	(117)	-	(140)	(71)
Net cash (used in)/provided by financing activities	<u>(117)</u>	<u>-</u>	<u>31,827</u>	<u>(71)</u>
(Decrease)/increase in cash and cash equivalents	(5,563)	(2,235)	19,516	(7,541)
Cash and cash equivalents - Beginning of period	38,729	17,475	13,650	22,781
Cash and cash equivalents - End of period	<u>\$ 33,166</u>	<u>\$ 15,240</u>	<u>\$ 33,166</u>	<u>\$ 15,240</u>
Non-cash deferred issuance cost (warrant value)	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 255</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, 2020 and 2019**  
**(U.S. dollars and shares in thousands)**  
**(Unaudited)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number (Note 5)	Amount				
<b>Balance at December 31, 2019</b>	19,896	\$ 106,392	\$ 48,271	\$ (144,031)	\$ 1,243	\$ 11,875
Stock options issued to employees	-	-	391	-	-	391
Stock options issued to contractors	-	-	21	-	-	21
Net loss	-	-	-	(3,826)	-	(3,826)
<b>Balance at March 31, 2020</b>	19,896	106,392	48,683	(147,857)	1,243	8,461
Stock options issued to employees	-	-	522	-	-	522
Stock options issued to contractors	-	-	21	-	-	21
Issuance of securities	5,460	31,967	-	-	-	31,967
Net loss	-	-	-	(4,845)	-	(4,845)
<b>Balance at June 30, 2020</b>	25,356	138,359	49,226	(152,702)	1,243	36,126
Stock options issued to employees	-	-	1,238	-	-	1,238
Stock options issued to contractors	-	-	21	-	-	21
Exercise of options	454	1,373	(1,373)	-	-	-
Net loss	-	-	-	(6,200)	-	(6,200)
<b>Balance at September 30, 2020</b>	<u>25,810</u>	<u>\$ 139,732</u>	<u>\$ 49,112</u>	<u>\$ (158,902)</u>	<u>\$ 1,243</u>	<u>\$ 31,185</u>
<b>Balance at December 31, 2018</b>	19,896	\$ 106,392	\$ 44,934	\$ (131,256)	\$ 1,243	\$ 21,313
Stock options issued to employees	-	-	221	-	-	221
Stock options issued to contractors	-	-	43	-	-	43
Warrants issued to consultants	-	-	255	-	-	255
Net loss	-	-	-	(2,626)	-	(2,626)
<b>Balance at March 31, 2019</b>	19,896	106,392	45,453	(133,882)	1,243	19,206
Stock options issued to employees	-	-	1,669	-	-	1,669
Stock options issued to contractors	-	-	331	-	-	331
Net loss	-	-	-	(4,730)	-	(4,730)
<b>Balance at June 30, 2019</b>	19,896	106,392	47,453	(138,612)	1,243	16,476
Stock options issued to employees	-	-	314	-	-	314
Stock options issued to contractors	-	-	21	-	-	21
Net loss	-	-	-	(1,809)	-	(1,809)
<b>Balance at September 30, 2019</b>	<u>18,896</u>	<u>\$ 106,392</u>	<u>\$ 47,788</u>	<u>\$ (140,421)</u>	<u>\$ 1,243</u>	<u>\$ 15,002</u>

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

## 1. Nature of Business and Going Concern

Fennec Pharmaceuticals Inc. (“Fennec,” the “Company,” “we,” “us,” or “our”) is a biopharmaceutical company focused on the development of PEDMARK<sup>TM</sup> (a unique formulation of sodium thiosulfate) for the prevention of platinum-induced ototoxicity in pediatric cancer patients. We incorporated under the Canada Business Corporations Act (“CBCA”) in September 1996. Effective on August 25, 2011, the Company continued from the CBCA to the Business Corporations Act (British Columbia) (the “Continuance”). The Continuance was approved by our shareholders at our June 2011 Annual and Special Meeting and by resolution of the Board of Directors on August 10, 2011. 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 formed in 2018. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

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

During the three and nine-months ended September 30, 2020, the Company incurred a loss from operations of \$5,859 and \$14,539, respectively. At September 30, 2020, the Company had an accumulated deficit of \$158,902 and had experienced negative cash flows from operating activities during the three and nine-months ended September 30, 2020 in the amount of \$5,446 and \$12,311, respectively.

On May 5, 2020, the Company announced the completion of an underwritten public offering of 4,800,000 common shares at a public offering price of \$6.25 per share. In addition, Fennec issued an additional 660,204 common shares in connection with the partial exercise of the underwriters’ over-allotment option. The approximate total gross proceeds from the offering was \$31,967 (\$34,100 net of commissions, fees and issue costs).

On February 1, 2019, Fennec entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, an Arizona corporation, pursuant to which the Bank agreed to loan \$12,500 to the Company, to be made available upon New Drug Application (NDA) approval of PEDMARK by no later than September 30, 2020. The proceeds from the loan will be used for working capital purposes and to fund general business requirements in accordance with the terms of the Loan and Security Agreement. Interest under the Term Loans shall bear interest, on the outstanding daily balance thereof, at a floating per annum rate equal to the Effective Interest Rate (as defined in the Loan and Security Agreement) which is equal to the sum of the Prime Rate published in the Wall Street Journal (currently 3.25%) plus one percent (1.00%). The debt facility is to have interest-only monthly payments due for the first eighteen months from the funding date and then monthly principal and interest payments are due through the remainder of the term which has a maturity date of October 1, 2023. In connection with the facility, Fennec granted Bridge Bank a warrant to purchase up to 39 common shares at an exercise price of \$6.80 per common share, for a term of ten years from the date of issuance, subject to early termination under certain conditions.

On June 26, 2020, Fennec announced an amendment to the Loan and Security Agreement with Bridge Bank. This amendment provides Fennec with an \$18,000 debt facility comprised of two term loans. Term Loan A consists of \$12,500 to be funded upon New Drug Application NDA approval of PEDMARK<sup>TM</sup> in the U.S. to be made available upon NDA approval of PEDMARK by no later than December 31, 2020 and Term Loan B consists of \$5,500 to be funded upon the occurrence of a revenue event in 2021. The interest-only period for the facility has the ability to be extended from 18 months to 24 months from the funding of Term Loan A, provided that Term Loan B is funded, and certain conditions are met. The fee in connection with Loan B, can either be 2.13% of the Loan B amount in cash, or the Company can issue a warrant with a value equal to 3.25% of the Loan B amount. On August 6, 2020, the Company paid cash for the extended facility. These statements reflect that fee being settled with cash instead of a warrant. Under Accounting Standards Codification (“ASC”) 470-50, Modifications and Extinguishments, the amendment was considered a modification. As such, the Company had been amortizing the loan fee and the value of the warrant over the remainder of the loan term. Following the receipt of the U.S. Food and Drug Administration’s (FDA) Complete Response Letter (CRL), management decided to fully amortize the remaining portions of the loan fee and the value of the warrants.

Fennec Pharmaceuticals Inc.  
Notes to Unaudited Condensed Consolidated Financial Statements  
September 30, 2020  
(All dollar amounts shown in thousands)

On August 10, 2020, the Company received a CRL from the FDA regarding its New Drug Application (NDA) for PEDMARK<sup>TM</sup>. According to the CRL, after recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, the FDA identified deficiencies that are required to be resolved prior to the approval of PEDMARK<sup>TM</sup>. Importantly, no clinical safety or efficacy issues were identified during the review and there is no requirement for further clinical data. The Company plans to work closely with the third-party drug manufacturer and the FDA to fully address the CRL and plan to resubmit the NDA for PEDMARK<sup>TM</sup> as quickly as possible. As a result of the FDA's CRL the anticipated product launch did not occur as of September 30, 2020 and thus the Bridge Bank Term Loan A has not yet been funded. The Company does not believe it will receive FDA approval by December 31, 2020 and thus has fully amortized the deferred asset associated with Term Loan A. Furthermore, the Company believes the delay in approval will mean it will not be able to meet the revenue target to fund Term Loan B. As such, the deferred asset associated with Term Loan B has been expensed. The Company is currently in negotiations with Bridge Bank to receive an extension on both Term Loan A and B.

The Company believes the funds raised in the public offering which closed in May 2020, provides sufficient funding for the Company to carry-out its planned activities including potential NDA approval and the commencement of commercialization efforts for at least the next twelve months as it continues its strategic development of PEDMARK<sup>TM</sup>.

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

## 2. Significant Accounting Policies

### Basis of presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with US GAAP and are the responsibility of the Company's management. These unaudited interim condensed consolidated financial statements do not include all of the information and notes required by US GAAP for annual financial statements. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited 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, 2019. 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, 2019. These unaudited interim condensed consolidated financial statements have been prepared in U.S. dollars. All amounts presented are in thousands except for per share amounts.

### Use of estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the 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, 2020 and to state fairly the results for the periods presented. The most significant estimates utilized during the quarter ended September 30, 2020 included estimates necessary to value grants of stock options to employees and various contractors, disclosed in Note 4.

Fennec Pharmaceuticals Inc.  
Notes to Unaudited Condensed Consolidated Financial Statements  
September 30, 2020  
(All dollar amounts shown in thousands)

**New accounting pronouncements**

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 removes certain disclosures, modifies certain disclosures and adds additional disclosures. The ASU was effective for us on January 1, 2020, and interim periods within that fiscal year. Certain disclosures in ASU 2018-13 would need to be applied on a retrospective basis and others on a prospective basis. The Company concluded after evaluation, that the impact of ASU 2018-13 on our consolidated financial statements and disclosures was de minimis.

In August 2020, FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which, among other things, provides guidance on how to account for contracts on an entity’s own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity’s own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder’s rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity’s own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective of modified retrospective basis. This ASU is effective January 1, 2022 and interim periods presented. Early adoption of the ASU is permitted by the Company effective January 1, 2021. The Company is in the process of assessing the adoption of the ASU on the Company’s financial statements.

**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, 2020, the Company had \$33,166 in cash, savings and money market accounts (\$13,650 at December 31, 2019). At September 30, 2020, the Company held \$19 in cash of which \$11 (as presented in U.S. dollars) was in Canadian dollars (\$24 at December 31, 2019 as presented in U.S. dollars). At September 30, 2020, the Company held \$33,147 in money market investments. Money market investments typically have minimal risks. The Company has not experienced any loss or write-down of its money market investments since inception.

**3. Earnings 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 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:

	<b>Three Months Ended September 30,</b>		<b>Nine-month Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
<b>Numerator:</b>				
Net (loss)	\$ (6,200)	\$ (1,809)	\$ (14,871)	\$ (9,165)
<b>Denominator:</b>				
Weighted-average common shares, basic	25,598	19,896	22,969	19,896
Dilutive effect of stock options	-	-	-	-
Dilutive effect of warrants	-	-	-	-
Incremental dilutive shares	-	-	-	-
Weighted-average common shares, dilutive	25,598	19,896	22,969	19,896
Net (loss) per share, basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.09)</u>	<u>\$ (0.64)</u>	<u>\$ (0.46)</u>

Fennec Pharmaceuticals Inc.  
Notes to Unaudited Condensed Consolidated Financial Statements  
September 30, 2020  
(All dollar amounts shown in thousands)

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-month Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Options to purchase common stock	3,095	3,018	3,095	3,018
Warrants to purchase common stock	39	39	39	39

#### 4. Stockholders' Equity

##### Authorized capital stock

The Company's authorized capital stock consists of an unlimited number of shares of no-par common stock.

##### Warrants to Purchase Common Stock

During the three and nine-months ended September 30, 2020, there were no warrants issued or exercised. During the three and nine-months ended September 30, 2019, the Company issued warrants to purchase common stock priced in U.S. dollars with a weighted average price of \$6.80. These warrants have not been exercised and have weighted average remaining life of 8.58 years as of September 30, 2020. The following table details the Company's warrant activity from December 31, 2019:

<u>Investor Warrants</u>	<u>Common Shares Issuable Upon Exercise of Outstanding Warrants</u>	<u>Weighted-Average Exercise Price \$USD</u>
Outstanding December 31, 2019	39	6.80
Issued	-	-
Outstanding March 31, 2020	39	6.80
Issued	-	-
Outstanding June 30, 2020	39	6.80
Issued	-	-
Outstanding September 30, 2020	39	6.80
<b>Total</b>	<b>39</b>	<b>6.80</b>

<u>Investor Warrants</u>	<u>Common Shares Issuable Upon Exercise of Outstanding Warrants</u>	<u>Weighted-Average Exercise Price \$USD</u>
Outstanding December 31, 2018	-	-
Issued	39	6.80
Outstanding March 31, 2019	39	6.80
Issued	-	-
Outstanding June 30, 2019	39	6.80
Issued	-	-
Outstanding September 30, 2019	39	6.80
<b>Total</b>	<b>39</b>	<b>6.80</b>

The value of warrants issued was estimated using the Black-Scholes option pricing model using the following assumptions in the table below. The expected volatility was determined using historical volatility of our stock based on the contractual life of the award.

Fennec Pharmaceuticals Inc.  
Notes to Unaudited Condensed Consolidated Financial Statements  
September 30, 2020  
(All dollar amounts shown in thousands)

<b>Black-Scholes Model Assumptions</b>	<b>Valuation Assumptions February 1, 2019</b>
Expected dividend	0.00%
Risk free rate	2.70%
Expected volatility	179%
Expected life	10 years

### Stock option plan

On June 22, 2020, shareholders of the Company approved a resolution adopting the Equity Incentive Plan (the “Plan”). This Plan replaces the Amended and Restated Stock Option Plan passed by shareholders in 2019. The Plan expands the types of instruments which may be issued as incentive compensation to employees, directors and designated contractors. In addition to stock options, the Plan may also issue: stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards and dividend equivalent rights. The Company believes this Plan gives it the ability to align incentives with strategic objectives.

The Compensation Committee of the Board of Directors administers the Company’s Plan. The Compensation Committee designates eligible participants to be included under the Plan and approves the number of options to be granted from time to time under the Plan. Currently, the maximum number of option shares issuable is twenty-five percent (25%) of the total number of issued and outstanding shares of common stock. Based upon the current shares outstanding, a maximum of 6,452 options are authorized for issuance 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 for the three and nine-month periods ended September 30, 2020 and 2019.

	<b>Three Months Ended September 30,</b>		<b>Nine-month Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Contractor options expense recognized	\$ 21	\$ 21	\$ 63	\$ 395
Employee options expense recognized	1,238	314	2,151	2,204
<b>Total option expense recognized</b>	<b>\$ 1,259</b>	<b>\$ 335</b>	<b>\$ 2,214</b>	<b>\$ 2,599</b>

### Stock option activity

The following is a summary of option activity for each of the quarterly periods in fiscal year 2020 for stock options denominated in U.S. dollars:

<b>US Denominated Options</b>	<b>Number of Options (thousands)</b>	<b>Weighted-Average Exercise Price \$USD</b>
<b>Outstanding December 31, 2019</b>	2,440	\$ 3.59
Granted	-	-
<b>Outstanding at March 31, 2020</b>	2,440	\$ 3.59
Granted	475	6.97
<b>Outstanding at June 30, 2020</b>	2,915	\$ 4.52
Granted	180	6.17
<b>Outstanding at September 30, 2020</b>	3,095	\$ 4.62

During the three-month period ended September 30, 2020, there were 180 US denominated options issued. For the nine months ended September 30, 2020 there were 655 options issued. Of the 3,095 US denominated options granted and outstanding at September 30, 2020, 2,230 are fully vested and exercisable.

The following is a summary of option activity for each of the quarterly periods in fiscal year 2019 for stock options denominated in U.S. dollars:

<b>US Denominated Options</b>	<b>Number of Options (thousands)</b>	<b>Weighted-Average Exercise Price \$USD</b>
<b>Outstanding December 31, 2018</b>	1,850	\$ 3.80
Granted	-	-
<b>Outstanding at March 31, 2019</b>	1,850	\$ 3.80
Granted	345	4.69
<b>Outstanding at June 30, 2019</b>	2,195	\$ 3.94
Granted	175	4.74
<b>Outstanding at September 30, 2019</b>	2,370	\$ 4.00

Fennec Pharmaceuticals Inc.  
Notes to Unaudited Condensed Consolidated Financial Statements  
September 30, 2020  
(All dollar amounts shown in thousands)

The following is a summary of option activity for the three and nine-month periods ended September 30, 2020 for stock options denominated in Canadian dollars:

<b>Canadian Denominated Options</b>	<b>Number of Options (thousands)</b>	<b>Weighted-Average Exercise Price \$CAD</b>
<b>Outstanding December 31, 2019</b>	648	\$ 2.43
<b>Granted</b>	-	-
<b>Outstanding at March 31, 2020</b>	648	\$ 2.43
<b>Granted</b>	-	-
<b>Outstanding at June 30, 2020</b>	648	\$ 2.43
<b>Exercised</b>	(648)	2.43
<b>Outstanding at September 30, 2020</b>	-	-

For the three and nine-month periods ended September 30, 2020, there was no issuance activity related to Canadian dollar denominated options. During the period ended September 30, 2020, all 648 outstanding options denominated in Canadian dollars were fully exercised pursuant to a cashless exercise. As a result, the Company did not receive any cash and issued 454 shares.

The following is a summary of option activity for the three and nine-month periods ended September 30, 2019 for stock options denominated in Canadian dollars:

<b>Canadian Denominated Options</b>	<b>Number of Options (thousands)</b>	<b>Weighted-Average Exercise Price \$CAD</b>
<b>Outstanding December 31, 2018</b>	648	\$ 2.43
<b>Granted</b>	-	-
<b>Outstanding at March 31, 2019</b>	648	\$ 2.43
<b>Granted</b>	-	-
<b>Outstanding at June 30, 2019</b>	648	\$ 2.43
<b>Granted</b>	-	-
<b>Outstanding at September 30, 2019</b>	648	\$ 2.43

#### Valuation assumptions

The value of options granted were estimated using the Black-Scholes option pricing model using the following assumptions in the table below. The expected volatility was determined using historical volatility of our stock based on the contractual life of the award. There were 180 options issued during the three months ended September 30, 2020, (175 for the same period in 2019). Assumptions for the valuation of the option grants are described in the table below:

<b>Black-Scholes Model Assumptions</b>	<b>Three Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
Expected dividend	0.00%	0.00%
Risk free rate	0.69%	1.63%
Expected volatility	141%	151%
Expected life	10 years	10 years

## 5. Fair Value Measurements

The Company adopted the Fair Value Measurements and Disclosure Topic of the FASB in 2011. This Topic applies to certain assets and liabilities that are being measured and reported on a fair value basis. The Topic defines fair value, establishes a framework for measuring fair value in accordance with US GAAP, and expands disclosure about fair value measurements. This Topic enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. The Topic requires that financial assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

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

**Fair Value Measurement at September 30, 2020 and December 31, 2019**  
(in thousands)

	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2020	2019	2020	2019	2020	2019	2020	2019
	<b>Assets</b>							
Cash and cash equivalents	19(1)	347(1)	33,147(2)	13,303(2)	-	-	33,166	13,650

(1) The Company held approximately \$19 in cash as of September 30, 2020, of which approximately \$11 was in Canadian funds (translated into U.S. dollars). As of December 31, 2019, the Company held approximately \$347 in cash of which approximately \$30 was in Canadian funds (translated into U.S. dollars).

(2) These amounts are held in a Money Market account.

## 6. Commitments and Contingencies

### Oregon Health & Science University Agreement

On February 20, 2013, Fennec entered into a new exclusive license agreement with OHSU for exclusive worldwide license rights to intellectual property directed to thiol-based compounds, including sodium thiosulfate 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 entered in the OHSU Agreement including but not limited to the royalty rate on net sales for licensed products, royalty rate from sublicensing of the licensed technology and the fee payable upon the regulatory approval of a licensed product.

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. Sodium thiosulfate is currently protected by methods of use patents that the Company exclusively licensed from OHSU that expire in Europe in 2021 and that expire in the United States in 2038. The OHSU Agreement is terminable by either Fennec or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. Fennec also has the right to terminate the OHSU Agreement at any time upon 60 days prior written notice and payment of all fees due to OHSU under the OHSU Agreement.

### **Class Action Suit**

Following the U.S. Food and Drug Administration's (FDA's) Complete Response Letter (CRL) regarding its New Drug Application (NDA) for PEDMARK<sup>TM</sup> as described in Note 1, a putative lawsuit was filed against us purportedly on behalf of purchasers of the Company's securities between February 11, 2020 and August 10, 2020. The lawsuit seeks to recover damages for Fennec investors under federal securities laws. While we believe that the lawsuit is without merit and intend to vigorously defend against it, the lawsuit is in its early stages and no assessment can be made as to their likely outcome or whether the outcome will be material to us. This litigation, and any other securities class actions that may be brought against us, could result in substantial costs and a diversion of our management's attention and resources.

### **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 (as of November 5, 2020, \$430,000). 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 nine-months of salary (as of November 5, 2020, \$155,875). In the event of her termination with us other than for cause, we will be obligated to pay Ms. Goel a one-time severance payment equal to three months of salary (as of November 5, 2020, \$90,000)

### **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 \$400 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 \$1,150. The Company was required to pay a security deposit of \$2,300, which is the equivalent to two months of rent. The Office Service Agreement commenced on January 27, 2020 and terminated on July 31, 2020, where it automatically renewed for a successive period equal to the original term. Either party is able to terminate the agreement by providing no less than three months' advance written notice of termination.

### **COVID-19**

The Company's operations may be affected by the recent and ongoing outbreak of the coronavirus disease 2019 (COVID-19) which was declared a pandemic by the World Health Organization in March 2020. The ultimate disruption which may be caused by the outbreak is uncertain; however, it may result in a material adverse impact on the Company's financial position, operations and cash flows. Possible effects may include, but are not limited to, disruption to the Company's product launch which includes the ability of sales reps to communicate with oncologists, absenteeism in the Company's labor workforce, unavailability of products and supplies used in operations, and a decline in value of assets held by the Company, including inventories, property and equipment, and marketable securities. COVID-19 has not had a material effect on the Company's operations to date as the Company has 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.

### **Loan Security Agreement**

On February 1, 2019, the Company's wholly owned subsidiary Fennec Pharmaceuticals Inc. entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Bridge Bank, a division of Western Alliance Bank, an Arizona corporation (the "Bank"), pursuant to which the Bank agreed to loan \$12,500 to Fennec Pharmaceuticals, Inc., to be made available upon NDA approval of PEDMARK by no later than September 30, 2020. The proceeds from the loan will be used for working capital purposes and to fund general business requirements in accordance with the terms of the Loan and Security Agreement. Interest under the Term Loans shall bear interest, on the outstanding daily balance thereof, at a floating per annum rate equal to the Effective Interest Rate (as defined in the Loan and Security Agreement) which is equal to the sum of the Prime Rate published in the Wall Street Journal (currently 3.25%) plus one percent (1.00%). The debt facility is to have interest-only monthly payments due for the first eighteen months from the funding date and then monthly principal and interest payments are due through the remainder of the term which has a maturity date of October 1, 2023. In connection with the facility, Fennec granted Bridge Bank a warrant to purchase up to 39 common shares at an exercise price of \$6.80 per common share, for a term of ten years from the date of issuance, subject to early termination under certain conditions.

On June 26, 2020, Fennec announced an amendment to the Loan and Security Agreement with Bridge Bank. This amendment provides Fennec with an \$18,000 debt facility comprised of two term loans. Term Loan A consists of \$12,500 to be funded upon NDA approval of PEDMARK<sup>TM</sup> in the U.S. by no later than December 31, 2020 and Term Loan B consists of \$5,500 to be funded upon the occurrence of a revenue event in 2021. The interest-only period for the facility has the ability to be extended from 18 months to 24 months from the funding of Term Loan A, provided that Term Loan B is funded, and certain conditions are met. Under Accounting Standards Codification ("ASC") 470-50, Modifications and Extinguishments, the amendment was considered a modification. As such, the Company had been amortizing the loan fee and the value of the warrant over the remainder of the loan term. Following the receipt of the FDA's CRL, management decided to fully amortize the remaining portions of the loan fee and the value of the warrants.

The combined value of the granted warrants and the associated costs to secure the loan facility (approximately \$466 thousand) were capitalized on the balance sheet as a long-term asset. As a result of the CRL and delays with FDA approval and product launch, the Company does not believe it will meet the conditions to fund Term Loan A or B and thus has fully amortized all remaining unamortized value associated with the deferred issuance costs. During the quarter ended September 30, 2020, the Company recorded amortization expense of roughly \$355 and a total of \$466 has been amortized as of September 30, 2020.

## 7. Subsequent Events

### S-3 Registration and At The Market Facility

On October 30, 2020, the Company filed a S-3 registration of common shares (File No. 333-249775) pursuant to which the Company may offer from time to time, shares of our common stock having an aggregate offering price of up to \$90.0 million. Under the Sales Agreement, the Company may sell shares by any method permitted by law and deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act, as amended, including sales made directly on the NASDAQ, on any other existing trading market for our common stock or to or through a market maker. The S-3 (File No. 333-249775) was declared effective on November 10, 2020.

Further, on October 30, 2020, the Company entered into an At The Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC ("HCW"), pursuant to which the Company may sell and issue its common shares (the "Shares") from time to time through HCW, as the Company's sales agent (the "ATM Offering"). The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Agreement or terminate the Agreement. The Shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-221093), which was declared effective on November 3, 2017. As of the date of this filing, there have been no such sales.

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

### **CAUTIONARY STATEMENT**

The discussion below contains forward-looking statements regarding our financial condition and our results of operations that are based upon our annual consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles within the United States, or U.S. GAAP, and applicable U.S. Securities and Exchange Commission, or SEC, regulations for financial information. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, income and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that we believe to be reasonable.

#### **Overview**

#### **Lead Product Candidate PEDMARK™**

The following is our only lead product candidate in the clinical stage of development:

- PEDMARK™ (a unique formulation of sodium thiosulfate) – PEDMARK has announced results of two Phase 3 clinical trials for the prevention of cisplatin induced hearing loss, or ototoxicity in children including the pivotal Phase 3 study SIOPEL 6, “A Multicentre Open Label Randomised Phase 3 Trial of the Efficacy of Sodium Thiosulfate in Reducing Ototoxicity in Patients Receiving Cisplatin Chemotherapy for Standard Risk Hepatoblastoma,” and the proof of concept Phase 3 study “A Randomized Phase 3 Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children”. COG ACCL0431 final results were published in the Lancet Oncology in 2016. SIOPEL 6 final results were published in the New England Journal of Medicine in June 2018.

We continue to focus the Company’s resources on the development of PEDMARK™.

We have licensed from OHSU intellectual property rights for the use of PEDMARK™ as a chemoprotectant, and are developing PEDMARK™ as a protectant against the hearing loss often caused by platinum-based anti-cancer agents in children. Preclinical and clinical studies conducted by OHSU and others have indicated that PEDMARK™ can effectively reduce the incidence of hearing loss caused by platinum-based anti-cancer agents.

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. 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. 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.

The Company estimates in the U.S. and Europe that over 10,000 children with solid tumors are treated with platinum agents. The vast majority of these newly diagnosed tumors are localized and classified as low to intermediate risk in nature. These localized cancers may have overall survival rates of greater than 80%, further emphasizing the importance of quality of life after treatment. 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. 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 at critical stages of development lack speech language development and literacy, and older children and adolescents lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

We initiated our rolling New Drug Application (NDA) for PEDMARK™ for the prevention of ototoxicity induced by cisplatin chemotherapy patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors in December 2018. Fennec announced that it has submitted full completion of the NDA in February 2020. On April 13, 2020 Fennec announced that the U.S. Food and Drug Administration (“FDA”) had accepted for filing and granted Priority Review for Fennec’s New Drug Application for PEDMARK. The FDA set a Prescription Drug Fee Act (PDUFA) target action date of August 10, 2020 for the completion of the FDA’s review. On August 10, 2020 the Company announced that it received a Complete Response Letter (CRL) from the FDA regarding its NDA for PEDMARK. Further, subsequent to the CRL the Company is pleased with the recent constructive and collaborative Type A meeting with the FDA and plans to work closely with the third-party drug manufacturer and the FDA to fully address the CRL and plans to resubmit the NDA for PEDMARK™ as quickly as possible. Importantly, no clinical safety or efficacy issues were identified during the review and there is no requirement for further clinical data.

In March 2018, PEDMARK™ received Breakthrough Therapy and Fast Track designations from the FDA. Further, PEDMARK™ has received Orphan Drug Designation in the US in this setting.

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 the Company's 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. The Company was also advised that sodium thiosulfate (tradename to be determined) is eligible for submission of an application for a Pediatric Use Marketing Authorization (PUMA). Therefore, this decision allows Fennec 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. The 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. In February 2020, Fennec announced that it has 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.

## **SIOPEL 6**

In October 2007, we announced that our collaborative partner, the International Childhood Liver Tumour Strategy Group, known as SIOPEL, a multi-disciplinary group of specialists under the umbrella of the International Society of Pediatric Oncology, had launched a randomized Phase 3 clinical trial SIOPEL 6 to investigate whether sodium thiosulfate reduces hearing loss in standard risk hepatoblastoma (liver) cancer patients receiving cisplatin as a monotherapy.

The study was initiated in October 2007 initially in the United Kingdom and completed enrollment at the end of 2014. 52 sites from 11 countries, enrolled 109 evaluable patients. Under the terms of our agreement, SIOPEL conducts and funds all clinical activities and Fennec provides drug, drug distribution and pharmacovigilance, or safety monitoring, for the study. SIOPEL 6 was completed in December 2014 and the final results of SIOPEL 6 were published in *The New England Journal of Medicine* in June 2018.

The primary objectives of SIOPEL 6 are:

- To assess the efficacy of sodium thiosulfate to reduce the hearing impairment caused by cisplatin
- To carefully monitor any potential impact of sodium thiosulfate on response to cisplatin and survival

## **SIOPEL 6 - Results**

### **Background / Objectives:**

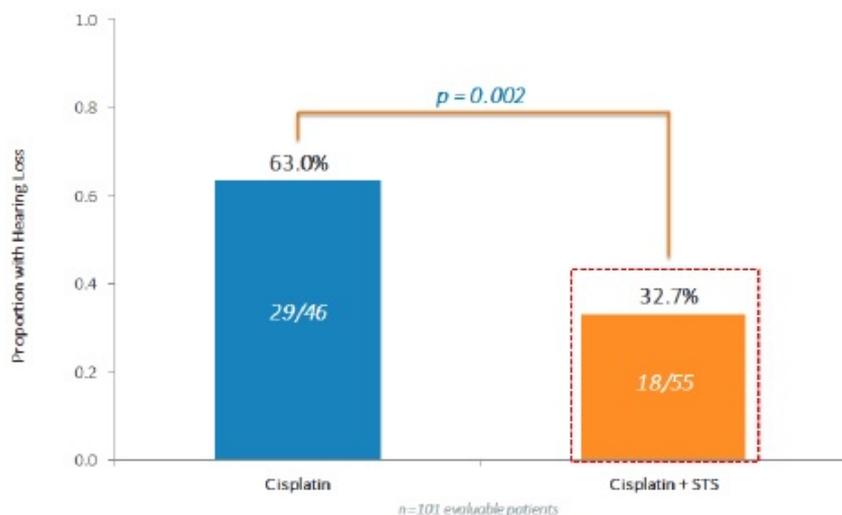
Background: Bilateral high-frequency hearing loss is a serious permanent side-effect of cisplatin therapy; particularly debilitating when occurring in young children. Sodium thiosulfate has been shown to reduce cisplatin induced hearing loss. SIOPEL 6 is a Phase 3 randomized trial to assess the efficacy of sodium thiosulfate in reducing ototoxicity in young children treated with cisplatin (Cis) for SR-HB.

## Design / Methods:

Methods: Newly diagnosed patients with SR-HB, defined as tumour limited to PRETEXT I, II or III, no portal or hepatic vein involvement, no intra-abdominal extrahepatic disease, AFP >100ng/ml and no metastases, were randomized to Cis or Cis+Sodium thiosulfate (STS) for 4 preoperative and 2 postoperative courses. Cisplatin 80mg/m<sup>2</sup> was administered over 6 hours, STS 20g/m<sup>2</sup> was administered intravenously over 15 minutes exactly 6 hours after stopping cisplatin. Tumour response was assessed after 2 and 4 preoperative cycles with serum AFP and liver imaging. In case of progressive disease (PD), sodium thiosulfate was to be stopped and doxorubicin 60mg/m<sup>2</sup> combined with cisplatin. The primary endpoint is centrally reviewed absolute hearing threshold, at the age of ≥3.5 years by pure tone audiometry.

## Results:

One hundred and nine randomized patients (52 Cisplatin only ("Cis") and 57 Cis+STS) are evaluable. The combination of Cis+STS was generally well tolerated. With a follow up time of 52 months for the patients the three-year Event Free Survival ("EFS") for Cis is 78.8% Cisplatin and 82.1% for the Cis + STS. The three-year Overall Survival ("OS") is 92.3% for Cis and 98.2% for Cis + STS. Treatment failure defined as Progressive Disease ("PD") at 4 cycles was equivalent in both arms. Among the first 101 evaluable patients, hearing loss occurred in 29/46=63.0% under Cis and in 18/55=33.0% under Cis +STS, corresponding to a relative risk of 0.52(P=0.002).



## Conclusions:

This randomized Phase 3 trial in SR-HB of cisplatin versus cisplatin plus sodium thiosulfate shows that the addition of sodium thiosulfate significantly reduces the incidence of cisplatin-induced hearing loss without any evidence of tumor protection.

## COG ACCL0431

In March 2008, we announced the activation of a Phase 3 trial with sodium thiosulfate to prevent hearing loss in children receiving cisplatin-based chemotherapy in collaboration with the Children's Oncology Group ("COG ACCL0431"). The goal of this Phase 3 study was to evaluate in a multi-centered, randomized trial whether sodium thiosulfate is an effective and safe means of preventing hearing loss in children receiving cisplatin-based chemotherapy for newly diagnosed germ cell, liver (hepatoblastoma), brain (medulloblastoma), nerve tissue (neuroblastoma) or bone (osteosarcoma) cancers. Eligible children, one to eighteen years of age, who were to receive cisplatin according to their disease-specific regimen and, upon enrollment in this study, were randomized to receive sodium thiosulfate or not. Efficacy of sodium thiosulfate was determined through comparison of hearing sensitivity at follow-up relative to baseline measurements using standard audiometric techniques. The Children's Oncology Group is responsible for funding the clinical activities for the study and we are responsible for providing the drug, drug distribution and pharmacovigilance, or safety monitoring, for the study. The trial completed enrollment of 131 pediatric patients in the first quarter of 2012. The final results of COG ACCL0431 were published in *Lancet Oncology* in December 2016.

## COG ACCL0431 - Results

COG Study ACCL0431, “A Randomized Phase 3 Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children,” finished enrollment of 131 patients of which 126 were eligible patients in Q1 2012. The patients had been previously diagnosed with childhood cancers.

The primary endpoint was to evaluate the efficacy of sodium thiosulfate for prevention of hearing loss in children receiving cisplatin chemotherapy (hypothesis: 50% relative reduction in hearing loss).

Secondary endpoints included:

- Compare change in mean hearing thresholds
- Compare incidence of other Grade 3/4 toxicities (renal and hematological)
- Monitor Event Free Survival (EFS) and Overall Survival (OS) in two groups

126 eligible subjects were enrolled with germ cell tumor (32), osteosarcoma (3029), neuroblastoma (26), medulloblastoma/pnet (26), hepatoblastoma (7) or other (5). Of these, 104 subjects (64 male and 29 <5 years old) were evaluable for the primary endpoint.

Subjects were randomized either to no treatment (control) or treatment with sodium thiosulfate 16 grams/m<sup>2</sup> IV over 15 minutes, 6 hours after each cisplatin dose. Hearing was measured using standard audiometry for age and data were reviewed centrally using American Speech-Language-Hearing Association criteria.

The proportion of subjects with hearing loss assessed at 4 weeks post the final cisplatin dose (primary endpoint).

- The proportion of hearing loss for sodium thiosulfate vs. Control was 28.6% (14/49) vs. 56.4% (31/55), respectively (p=0.004).
- In a predefined subgroup of patients less than 5 years old with 29 eligible subjects: sodium thiosulfate vs. Control was 21.4% (3/14) vs. 73.3% (11/15), respectively (p=0.005)

### Conclusions:

- Sodium thiosulfate protects against cisplatin-induced hearing loss in children across a heterogeneous range of tumor types with even stronger efficacy in the protocol predefined subgroup of patients under five years old and is not associated with serious adverse events attributed to its use.
- Further potential clinical use will be informed by the final results of SIOPEL 6 study.

### Capital Funding

We have not received and do not expect to have significant revenues from our product candidate until we are either able to sell our product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue.

We generated a net loss of approximately \$14,874 for the nine-months ended September 30, 2020 and a net loss of \$9,165 for the nine-months ended September 30, 2019. As of September 30, 2020, our accumulated deficit was approximately \$158,902 (\$144,031 at December 31, 2019).

On May 5, 2020, the Company announced the completion of an underwritten public offering of 4.8 million common shares at a public offering price of \$6.25 per share. In addition, Fennec issued an additional 0.66 million common shares in connection with the partial exercise of the underwriters' over-allotment option. The approximate total gross proceeds from the offering was \$34,100 (\$31,967 net of commissions, fees and issue costs).

On June 26, 2020, Fennec announced an amendment to the Loan and Security Agreement with Bridge Bank. This amendment provides Fennec with an \$18,000 debt facility comprised of two term loans. Term Loan A consists of \$12,500 to be funded upon NDA approval of PEDMARK<sup>TM</sup> in the U.S. by no later than December 31, 2020 and Term Loan B consists of \$5,500 to be funded upon the occurrence of a revenue event in 2021. The interest-only period for the facility has the ability to be extended from 18 months to 24 months from the funding of Term Loan A, provided that Term Loan B is funded, and certain conditions are met. Under Accounting Standards Codification (“ASC”) 470-50, Modifications and Extinguishments, the amendment was considered a modification. As such, the Company is amortizing the loan fee and the value of the warrant over the remainder of the loan term. The Company intends to use the proceeds from the loans to provide working capital for commercialization activities for PEDMARK<sup>TM</sup> upon NDA approval.

On August 10, 2020, the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for PEDMARK<sup>TM</sup>. According to the CRL, after recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, the FDA identified deficiencies that are required to be resolved prior to the approval of PEDMARK<sup>TM</sup>. Importantly, no clinical safety or efficacy issues were identified during the review and there is no requirement for further clinical data. The Company plans to work closely with the third-party drug manufacturer and the FDA to fully address the CRL and plan to resubmit the NDA for PEDMARK<sup>TM</sup> as quickly as possible. As a result of the FDA's CRL the anticipated product launch did not occur as of September 30, 2020 and thus the Bridge Bank Term Loan A has not yet been funded. The Company does not believe it will receive FDA approval by December 31, 2020 and thus has fully impaired the deferred asset associated with Term Loan A. Furthermore, the Company believes the delay in approval will mean it will not be able to meet the revenue target to fund Term Loan B. As such, the deferred asset associated with Term Loan B has been expensed. The Company is currently in negotiations with Bridge Bank to receive an extension on both Term Loan A and B.

We believe that our cash and cash equivalents as of September 30, 2020, which totaled \$33,166 will be sufficient to meet our cash requirements through the at least the next twelve months. Our projections of our capital requirements are subject to substantial uncertainty. More capital than we anticipated 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. Given current economic conditions, we might 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 drug development 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, salaries for research and development personnel, stock-based compensation, 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 of our drug development programs.

## Results of Operations

Three months ended September 30, 2020 versus three months ended September 30, 2019:

<b>In thousands of U.S. Dollars</b>	<b>Three Months Ended September 30, 2020</b>	<b>%</b>	<b>Three Months Ended September 30, 2019</b>	<b>%</b>	<b>Change</b>
<b>Operating expenses:</b>					
Research and development	\$ 1,368	23%	\$ 795	43%	\$ 573
General and administrative	4,491	77%	1,068	57%	3,423
Total operating expenses	<u>5,859</u>	100%	<u>1,863</u>	100%	<u>3,996</u>
<b>Loss from operations</b>	<u>(5,859)</u>		<u>(1,863)</u>		<u>(3,996)</u>
Other (loss)/gain	(8)		1		(9)
Amortization expense	(355)		(17)		(338)
Interest income and other	22		70		(48)
<b>Net loss</b>	<u>\$ (6,200)</u>		<u>\$ (1,809)</u>		<u>\$ (4,391)</u>

Research and development expenses increased by \$573 for the three months ended September 30, 2020 over the same period in 2019 as the Company's activities increased after the CRL from the FDA related to manufacturing and regulatory. General and administrative expenses increased by \$3,423 over same period in 2019 being driven mainly by the pre-commercialization efforts, non-cash equity remuneration and added headcount.

Other (loss)/gain was driven mainly by fluctuations in its foreign currency transactions. The Company has vendors that transact in Euros, Great British Pounds and Canadian Dollars. There was an increase of \$338 in amortization expense for the three months ended September 30, 2020 over the same period in 2019. This increase is mainly as a result of recognizing the complete impairment of both sections of the Term Loan Agreement on the balance sheet. Amortization expense is a non-cash expense and relates to amortization of the deferred issuance cost of the loan facilities with Bridge Bank. Amortization expense was \$355 and \$17 for the three months ended September 30, 2020 and 2019, respectively. Interest income was \$48 lower for the three months ended September 30, 2020 over the same period in 2019. This was driven mainly by a sharp decrease in interest rates for the three months ended September 30, 2020 over the same period in 2019.

In thousands of U.S. Dollars	Nine Months Ended		Nine Months Ended		Change
	September 30, 2020	%	September 30, 2019	%	
<b>Operating expenses:</b>					
Research and development	\$ 3,882	27%	\$ 4,435	47%	\$ (553)
General and administrative	10,657	73%	4,921	53%	5,736
Total operating expenses	14,539	100%	9,356	100%	5,183
<b>Loss from operations</b>	<b>(14,539)</b>		<b>(9,356)</b>		<b>(5,183)</b>
Other (loss)/gain	(4)		(9)		5
Amortization expense	(402)		(46)		(356)
Interest income and other	74		246		(172)
<b>Net loss</b>	<b>\$ (14,871)</b>		<b>\$ (9,165)</b>		<b>\$ (5,706)</b>

Total research and development expenses were down by \$553 for the nine-month period ended September 30, 2020 over the same period in 2019. This decrease relates primarily to the shift from research and development to pre-commercialization and product launch efforts for PEDMARK™ which took place in the first nine months of 2020. The increase in pre-commercialization and product launch efforts are reflected in the general and administrative cost increase of \$5,736 over the prior year in the same period in 2019. A large portion of this increase were from sales and marketing expenses which were up approximately \$4,600 over the same period in 2019 as the Company prepared for product launch. Salary and benefit expenses were up by approximately \$600 over same period in 2019. Items such as legal fees, consulting fees and investor relations accounted for an increase of \$500.

Other (loss)/gain increased by \$5 for the nine-months ended September 30, 2020 over the same period in 2019. For the nine-month period ended September 30, 2020 the Company recognized an increase of \$356 in amortization expense on the deferred issuance cost associated with the loan facilities arranged with Bridge Bank over the same period in 2019. This increase was primarily due to the decision to fully amortize the remaining balance of the loan facility asset after the Company decided it would not be able to meet the conditions of the loan facility. Presently, the Company is in negotiations with Bridge Bank to extend the dates associated with funding the facility. Interest income was down sharply \$172 over the same period in 2019, due to lower interest rates and lower average deposits.

#### Quarterly Information

The following table presents selected condensed financial data for each of the last eight quarters through September 30, 2020, as prepared under US GAAP (U.S. dollars in thousands, except per share information):

Period	Net (Loss)/Income for the Period	Basic Net (Loss)/Income per Common Share	Diluted Net (Loss)/Income per Common Share
December 31, 2018	(2,984)	(0.15)	(0.15)
March 31, 2019	(2,626)	(0.13)	(0.13)
June 30, 2019	(4,730)	(0.24)	(0.24)
September 30, 2019	(1,809)	(0.09)	(0.09)
December 31, 2019	(3,610)	(0.18)	(0.18)
March 31, 2020	(3,826)	(0.19)	(0.19)
June 30, 2020	(4,845)	(0.21)	(0.21)
September 30, 2020	(6,200)	(0.24)	(0.24)

## Liquidity and Capital Resources

U.S. Dollars in thousands

### Selected Asset and Liability Data:

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 33,166	\$ 13,650
Other current assets	904	234
Current liabilities	2,885	2,271
Working capital <sup>(1)</sup>	31,185	11,613
<sup>(1)</sup> [Current assets – current liabilities]		
<b>Selected equity:</b>		
Common stock	188,844	154,663
Accumulated deficit	(158,902)	(144,031)
Stockholders' equity	31,185	11,875

Cash and cash equivalents were \$33,166 on September 30, 2020 and \$13,650 at December 31, 2019. The increase in cash and cash equivalents between September 30, 2020 and December 31, 2019, is the result of the \$34,100 (gross proceeds) equity financing completed in May 2020. These cash inflows were offset by expenses related to our pre-commercialization expenses of PEDMARK™ and general and administrative expenses. The decrease in other current assets between September 30, 2020 and December 31, 2019 relates to the amortization of pre-paid Nasdaq annual listing fees and pre-paid Director's and Officer's Insurance.

Current liabilities increased primarily due to manufacturing and pre-commercialization activities associated with production and marketing of PEDMARK™ and related regulatory expenses.

Working capital increased between December 31, 2019 and September 30, 2020 by \$19,572. The increase was primarily as a result of the May 2020 financing. These cash inflows were offset by expenses related to our pre-commercialization activities of PEDMARK™ and general and administrative expenses.

The following table illustrates a summary of cash flow data for the three and nine-month periods of September 30, 2020 and 2019:

Dollar and shares in thousands	Three Months Ended September 30,		Nine-month Ended September 30,	
	2020	2019	2020	2019
<b>Selected cash flow data:</b>				
Net cash used in operating activities	\$ (5,446)	\$ (2,235)	\$ (12,311)	\$ (7,470)
Net cash provided by investing activities	-	-	-	-
Net cash (used in)/provided by financing activities	(117)	-	31,827	(71)
<b>(Decrease)/increase in cash and cash equivalents</b>	<b>\$ (5,563)</b>	<b>\$ (2,235)</b>	<b>\$ 19,516</b>	<b>\$ (7,541)</b>

Net cash used in operating activities for the three and nine-months ended September 30, 2020 was \$5,446 and \$12,311, respectively. This is compared to \$2,235 and \$7,470 during the same periods in 2019. These increases in cash outlays relate to the pre-commercialization activities of PEDMARK™ and regulatory submission activities relating to the NDA. The Company increased cash balances by \$31,967 from a public financing which it completed in May of 2020.

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

## Outstanding Share Information

The outstanding share data for our Company as of September 30, 2020 and December 31, 2019 was as follows (in thousands):

	September 30, 2020	December 31, 2019	Change
Common shares	25,810	19,896	5,914
Warrants	39	39	-
Stock options	3,095	3,088	7
Total	28,944	23,023	5,921

## 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, 2020, we had approximately \$33,166 in cash accounts (\$33,147 in money market accounts, and \$19 in checking accounts). We have not experienced any loss or write down of our money market investments since inception.

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 research and development, we have chosen to avoid investments of a trading or speculative nature.

## Off-Balance Sheet Arrangements

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<sup>TM</sup> 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-months ended September 30, 2020 and 2019 were \$1,368 and \$795, respectively and for the nine-months then ended, \$3,882 and \$4,435, respectively. For the three-months ended September 30, 2020 the Company has decreased its research and development expenses related to PEDMARK<sup>TM</sup> as the Company's efforts have shifted to pre-commercialization activities with some continued regulatory expenses associated with the rolling NDA submission of PEDMARK<sup>TM</sup>.

Our product candidate still requires significant, time-consuming and costly research and development, testing and regulatory clearances. In developing our product candidate, 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 our product candidate 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 Estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on assumptions and judgments that may be affected by commercial, economic and other factors. Actual results could differ from these estimates.

Our accounting policies are materially consistent with those presented in our annual consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019.

### **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. We do not hold any mortgaged-backed investments in our investment portfolio. 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.

At September 30, 2020, we had \$33,166 in money market investments and savings accounts as compared to \$13,303 at December 31, 2019; these investments typically have minimal risk. The financial markets had been volatile resulting in concerns regarding the recoverability of money market investments, but those conditions have stabilized. We have not experienced any loss or write down of our money market investments since inception.

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.

#### **Foreign Currency Exposure**

We are subject to foreign currency risks as we purchase goods and services which are denominated in 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, 2020, the Company held approximately \$14 thousand Canadian dollars (\$11 thousand as presented to U.S. dollars). At December 31, 2019, the Company held approximately \$30 thousand Canadian dollars (\$24 thousand 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, 2020.

**(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.**

In addition, on September 2, 2020, a putative class action lawsuit, *Chapman v. Fennec Pharmaceuticals Inc.*, was filed against the Company, Rostislav Raykov and Robert Andrade, in the United States District Court for the Middle District of North Carolina. The complaint alleges that prior to the receipt of the Complete Response Letter from the FDA, Fennec made materially false and misleading statements or omissions and failed to disclose material adverse facts about Fennec's business operations and prospects. The Company believes that the suit is without merit and intends to defend itself vigorously. Defendants are not required to respond to the lawsuit until the court appoints a lead plaintiff and a post-appointment complaint is filed or designated. The Company has not recorded a liability as of September 30, 2020 because a potential loss is not probable or reasonably estimable given the preliminary nature of the proceedings.

**Item 1A. Risk Factors.**

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 14, 2020 (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.

**Should the clinical development process be successfully completed, our ability to derive revenues from the sale of therapeutics will depend upon our first obtaining FDA as well as foreign regulatory approvals, all of which are subject to a number of unique risks and uncertainties.**

Even if we are able to demonstrate the safety and efficacy of our product candidate in clinical trials, if we fail to gain timely approval to commercialize PEDMARK from the FDA and other foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. The FDA or comparable regulatory authorities in other countries may delay, limit or deny approval of PEDMARK for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials; or with our interpretation of data from our preclinical studies or clinical trials; or may otherwise take the position that PEDMARK fails to meet the requirements and standards for regulatory approval. There are numerous FDA personnel assigned to review different aspects of a NDA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control ("CMC"), or other data and information, and the development and provision of these data and information may be time consuming and expensive. Regulatory approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval. On February 10, 2020, we submitted a New Drug Application ("NDA") to the FDA for PEDMARK for the prevention of ototoxicity associated with cisplatin chemotherapy in pediatric patients  $\geq 1$  month to 18 years of age with localized, non-metastatic, solid tumors. On April 10, 2020, we received notification from the FDA that the NDA was accepted for filing and the original application was granted Priority Review with a PDUFA target action date of August 10, 2020. On August 10, 2020, we received a Complete Response Letter ("CRL"). According to the CRL, after recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, the FDA identified deficiencies resulting in a Form 483, which is a list of conditions or practices that are required to be resolved prior to the approval of PEDMARK™. The Company has developed a detailed plan and has dedicated, and continues to commit, significant resources to addressing the CRL, while, in parallel, working with our third-party drug product manufacturer to be ready for re-inspection by the FDA. If the FDA determines that these actions were not sufficient, or based on the re-inspection FDA officials do not recommend approval relative to the drug product manufacturing facility, or if information deemed necessary by the FDA cannot be provided as part of our NDA submission or during the review period as deemed appropriate on a timely basis, such events could further delay the progress of our NDA and could require additional Company actions that cannot be completed during the review period which may adversely impact our business. Further, while we may develop a product candidate with the intention of addressing a large, unmet medical need, the FDA may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations.

Although historically we have been a research and development company, we currently plan to commercialize our lead product candidate internally rather than license such asset. There can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.

We have historically been engaged primarily in research and development activities, but plan to commercialize our lead product candidate, PEDMARK, ourselves. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercialization activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which can include problems relating to managing manufacturing and supply, reimbursement, marketing problems and additional costs. Our product candidate may require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the United States and other countries. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize PEDMARK, generate any significant revenues or ever achieve and maintain a substantial level of sales of our product.

***We are the target of securities litigation, which may be costly and time-consuming to defend.***

Following periods of market volatility in the price of a company's securities or the reporting of unfavorable news, security purchasers have often instituted class action litigation. This risk is especially relevant for us because pharmaceutical companies like us have experienced significant stock price volatility in recent years. Moreover, we were named in a putative securities class action complaint as a result of the decline in our stock price following the August 10, 2020 announcement that we had received a Complete Response Letter from the FDA regarding our NDA for PEDMARK™. See Item 1 under Legal Proceedings to our unaudited condensed consolidated financial statements included in this report. Regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer.

**There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances.**

Our certificate of incorporation limits, to the maximum extent permitted under British Columbia law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our bylaws provide that we will indemnify our officers and directors and may indemnify our employees and other agents to the fullest extent permitted by law. These provisions may be in some respects broader than the specific indemnification provisions under British Columbia law. The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of certain proceedings against them as to which they could be indemnified and to obtain directors' and officers' insurance.

We believe that our limitation of officer and director liability assists us to attract and retain qualified employees and directors. However, in the event an officer, a director or the board of directors commits an act that may legally be indemnified under British Columbia law, we will be responsible to pay for such officer(s) or director(s) legal defense and potentially any damages resulting there from. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly-held corporations, we believe that director indemnification is in our and our stockholders' best interests because it enhances our ability to attract and retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision-making.

Nevertheless, limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in our certificate of incorporation and bylaws could result in increased expenses. Our board of directors believes, however, that these provisions will provide a better balancing of the legal obligations of, and protections for, directors and will contribute positively to the quality and stability of our corporate governance. Our board of directors has concluded that the benefit to stockholders of improved corporate governance outweighs any possible adverse effects on stockholders of reducing the exposure of directors to liability and broadened indemnification rights.

**Our business and operations may be materially and adversely affected by the recent coronavirus outbreak.**

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States and Europe. In March 2020, the World Health Organization declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies. If the outbreak continues to spread, it may affect our operations and those of third parties on which we rely in a number of ways, including causing disruptions in the supply of our product candidate, the pending regulatory approval process and the conduct of current and planned preclinical and clinical studies. We may need to limit operations or implement limitations and may experience limitations in employee resources. There are risks that the coronavirus may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly. The extent to which the coronavirus impacts our results will depend on future developments, including, without limitation, new information that may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, all of which are highly uncertain and cannot be predicted.

Additionally, while the duration of and the potential economic impact caused by the coronavirus pandemic are difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to complete our regulatory submissions and clinical studies on a timely basis, or at all. For instance, our regulatory submissions may be temporarily delayed or paused, and the operations of our contracted third parties may be significantly delayed as well. The ultimate impact of the coronavirus pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or preclinical and clinical trial activities or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

**Natural disasters, epidemic or pandemic disease outbreaks, trade wars, political unrest or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future.**

A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the recent novel coronavirus outbreak), trade wars, political unrest or other events, could disrupt our business or operations or those of our manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. For example, many states recently ordered most businesses closed, mandating work-from-home arrangements where feasible, in response to the coronavirus pandemic. These limitations could negatively affect our business operations and continuity, and could negatively impact our development timelines and ability to timely perform basic business functions, including, without limitation, making SEC filings and preparing financial reports. If our operations or those of third parties with whom we conduct business are impaired or curtailed as a result of these events, the development and commercialization of our products and product candidate could be impaired or halted, which could have a material adverse impact on our business.

**Item 2. Recent Sales of Unregistered Securities.**

None

**Item 3. Default Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosure.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">31.1</a>	<a href="#">Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">31.2</a>	<a href="#">Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">32.1</a>	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">99.1</a>	<a href="#">Press Release for Quarter Ended September 30, 2020 (filed herewith).</a>
101.1	Interactive Data File

## 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 16, 2020

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

Date: November 16, 2020

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, 2020 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 16, 2020

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, 2020 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 16, 2020

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, 2020 (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 16, 2020

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

Date: November 16, 2020

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

---



## FENNEC PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2020 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

*~ The Company Continues to Work with the FDA and Its Third-Party Drug Product Manufacturer to Fully Address CRL and Prepare NDA Resubmission for PEDMARK™ ~*

*~ No Clinical Safety or Efficacy Issues Identified; No Additional Studies Required for PEDMARK™ ~*

*~ The Company Has Approximately \$33 Million in Cash and No Outstanding Debt ~*

**Research Triangle Park, NC, November 16, 2020** – Fennec Pharmaceuticals Inc. (Nasdaq:FENC; TSX: FRX), a specialty pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate) for the prevention of platinum-induced ototoxicity in pediatric patients, today reported its financial results for the third quarter ended September 30, 2020 and provided a business update.

“We are pleased with the recent constructive and collaborative Type A meeting with the FDA to discuss the path forward for resubmission of the New Drug Application (NDA) for PEDMARK™ for the prevention of life-long hearing loss for children receiving cisplatin chemotherapy,” said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. “Importantly, there were no clinical or safety issues identified in the complete response letter (CRL) and there are no requirements for additional clinical data within the CRL. We are working closely with the FDA and our third-party drug product manufacturer to fully address the CRL and plan to resubmit the NDA for PEDMARK™ with the goal of achieving regulatory approval and making PEDMARK™ commercially available to patients in need as quickly as possible.”

### **Financial Results for the Third Quarter 2020**

- **Cash Position** – Cash and cash equivalents were \$33.2 million as of September 30, 2020. The reduction in cash balance is the result of cash used for operating activities including regulatory activities of PEDMARK™ and expenses associated with commercial and operational launch preparation during the quarter. As of September 30, 2020, the Company has no funded debt.
  - **Research and Development (R&D) Expenses** – R&D expenses were \$1.4 million for the third quarter ended September 30, 2020, compared to \$0.8 million for the same period in 2019. The increase in R&D in the quarter was due to an increase in R&D expenses after the Complete Response Letter (CRL).
  - **General and Administrative (G&A) Expenses** – G&A expenses for the third quarter ended September 30, 2020, increased by \$3.4 million over the same period in 2019, reflecting the Company’s focus on commercialization readiness of PEDMARK™. The increase in G&A during the quarter was primarily due to commercialization readiness activities during the quarter leading up to the PDUFA date of PEDMARK in August 2020.
  - **Net Loss** – Net loss for the quarter ended September 30, 2020 was \$6.2 million (\$0.24 per share), compared to \$1.8 million (\$0.09 per share) for the same period in 2019.
-

## Financial Update

The selected financial data presented below are 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, 2020 and management's discussion and analysis of financial condition and results of operations will be available via [www.sec.gov](http://www.sec.gov) and [www.sedar.com](http://www.sedar.com). All values are presented in thousands unless otherwise noted.

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

	<b>Three Months Ended</b>	
	<b>September 30, 2020</b>	<b>September 30, 2019</b>
<b>Revenue</b>	\$ -	\$ -
<b>Operating expenses:</b>		
Research and development	1,368	795
General and administrative	4,491	1,068
<b>Loss from operations</b>	<u>(5,859)</u>	<u>(1,863)</u>
<b>Other (expense)/income</b>		
Amortization expense	(355)	(17)
Other loss	(8)	1
Net interest income	22	70
Total other income, net	<u>(341)</u>	<u>54</u>
<b>Net (loss)</b>	<u>\$ (6,200)</u>	<u>\$ (1,809)</u>
<b>Basic net (loss) per common share</b>	<u>\$ (0.24)</u>	<u>\$ (0.09)</u>
<b>Diluted net (loss) per common share</b>	<u>\$ (0.24)</u>	<u>\$ (0.09)</u>

---

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

	Unaudited September 30, 2020	Audited December 31, 2019
<b>Assets</b>		
Cash and cash equivalents	\$ 33,166	\$ 13,650
Other current assets	904	234
Non-current assets, net	-	262
<b>Total Assets</b>	<b>\$ 34,070</b>	<b>\$ 14,146</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities	\$ 2,885	\$ 2,271
Total stockholders' equity	31,185	11,875
<b>Total liabilities and stockholders' equity</b>	<b>\$ 34,070</b>	<b>\$ 14,146</b>

Working Capital

	Fiscal Year Ended	
	September 30, 2020	December 31, 2019
<b>Selected Asset and Liability Data:</b> (U.S. Dollars in thousands)		
Cash and cash equivalents	\$ 33,166	\$ 13,650
Other current assets	904	234
Current liabilities	(2,885)	(2,271)
<b>Working capital</b>	<b>\$ 31,185</b>	<b>\$ 11,613</b>
<b>Selected Equity:</b>		
Common stock & APIC	\$ 188,844	\$ 154,663
Accumulated deficit	(158,902)	(144,031)
Stockholders' equity	31,185	11,875

**About PEDMARK™**

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

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, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. Infants and young children that suffer ototoxicity at critical stages of development lack speech language development and literacy, and older children and adolescents lack social-emotional development and educational achievement.

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

The Marketing Authorization Application (MAA) for sodium thiosulfate (tradenam PEDMARQSI) is currently under evaluation by the European Medicines Agency (EMA). PEDMARK has received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018.

### **About Fennec Pharmaceuticals**

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development of PEDMARK™ for the prevention of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK has received Orphan Drug Designation in the U.S. for this potential use. 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 prevention of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit [www.fennecpharma.com](http://www.fennecpharma.com)

### **Forward Looking Statements**

*Except for historical information described in this press release, all other statements are forward-looking. These forward-looking statements include the Company's expectations regarding its interactions and communications with the FDA, including its expectation to discuss with the FDA the issues raised in the CRL and the Company's plans to address them. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such 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, Fennec's reliance on third party manufacturing, 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, 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, 2019 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. Fennec disclaims any obligation to update these forward-looking statements except as required by law.*

---

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

**For further information, please contact:**

**Investors:**

Rosty Raykov  
Chief Executive Officer  
Fennec Pharmaceuticals Inc.  
(919) 636-5144

**Media:**

Elixir Health Public Relations  
Lindsay Rocco  
(862) 596-1304  
[lrocco@elixirhealthpr.com](mailto:lrocco@elixirhealthpr.com)

---