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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2021
OR

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

For the transition period from____ to ____

Commission File Number: 001-32295

FENNEC PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

As of November 9, 2021, there were 26,006,853 common shares outstanding.

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PART 1: FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 24,335	$ 30,344
Prepaid expenses	1,232	797
Other current assets	412	276
Total current assets	25,979	31,417
Non-current assets		
Deferred issuance cost	508	466
Deferred issuance cost (amortization)	(473)	(466)
Total non-current assets	35	—
Total assets	$ 26,014	$ 31,417
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,154	$ 1,571
Accrued liabilities	860	776
Total current liabilities	2,014	2,347
Long term liabilities		
Term loan	5,000	—
Debt discount	(13)	—
Total long term liabilities	4,987	—
Total liabilities	7,001	2,347
Commitments and Contingencies (Note 6)		
Shareholders' equity:		
Common stock, no par value; unlimited shares authorized; 26,007 shares issued and outstanding (2020 -26,003)	140,780	140,733
Additional paid-in capital	52,049	49,234
Accumulated deficit	(175,059)	(162,140)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' equity	19,013	29,070
Total liabilities and shareholders' equity	$ 26,014	$ 31,417

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

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

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	1,242	1,368	4,458	3,882
General and administrative	2,931	4,491	8,558	10,657
Loss from operations	(4,173)	(5,859)	(13,016)	(14,539)
Other income/(expense):				
Other income/(loss)	(1)	(8)	(9)	(4)
Amortization expense	(8)	(355)	(8)	(402)
Unrealized gain on securities	39	—	137	—
Interest income	13	22	41	74
Interest expense	(55)	—	(64)	—
Total other (expense)/income	(12)	(341)	97	(332)
Net loss	$ (4,185)	$ (6,200)	$ (12,919)	$ (14,871)
Basic net loss per common share	$ (0.16)	$ (0.24)	$ (0.50)	$ (0.64)
Diluted net loss per common share	$ (0.16)	$ (0.24)	$ (0.50)	$ (0.64)
Weighted-average number of common shares outstanding basic	26,007	25,598	26,004	22,969
Weighted-average number of common shares outstanding diluted	26,007	25,598	26,004	22,969

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)

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Cash flows (used in) provided by:				
Operating activities:				
Net loss	$ (4,185)	$ (6,200)	$ (12,919)	$ (14,871)
Adjustments to reconcile net loss to net cash used in operating activities:				
Amortization of deferred issuance costs	8	355	8	402
Unrealized (gain) on securities	(39)	—	(137)	—
Stock-based compensation - contractors	—	21	9	63
Stock-based compensation - employees	917	1,238	2,830	2,151
Changes in operating assets and liabilities:				
Prepaid expenses	(823)	(734)	(435)	(674)
Other assets	(2)	—	—	4
Accounts payable	477	(71)	(417)	1,072
Accrued liabilities	689	(55)	84	(458)
Net cash used in operating activities	(2,958)	(5,446)	(10,977)	(12,311)
Financing activities:				
Issuance of shares, options exercise	—	—	24	—
Issuance of shares, net of issuance costs	—	—	—	31,967
Proceeds from long-term debt	—	—	5,000	—
Debt discount	—	—	(14)	—
Capitalized deferred issuance costs	—	(117)	(42)	(140)
Net cash (used in)/provided by financing activities	—	(117)	4,968	31,827
(Decrease)/increase in cash and cash equivalents	(2,958)	(5,563)	(6,009)	19,516
Cash and cash equivalents - Beginning of period	27,293	38,729	30,344	13,650
Cash and cash equivalents - End of period	$ 24,335	$ 33,166	$ 24,335	$ 33,166
Non-cash investing and financing activities:				
Deferred issuance cost (warrant value)	$ —	$ —	$ —	$ 255

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, 2021 and 2020
(U.S. dollars and shares in thousands)
(Unaudited)

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	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)
Balance at March 31, 2020	**19,896**	**$ 106,392**	**$ 48,683**	**$ (147,857)**	**$ 1,243**	**$ 8,461**
Stock options issued to consultants	—	—	522	—	—	522
Stock options issued to employees	—	—	21	—	—	21
Issuance of securities	5,460	31,967	—	—	—	31,967
Net loss	—	—	—	(4,845)	—	(4,845)
Balance at June 30, 2020	**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)
Balance at September 30, 2020	**25,810**	**$ 139,732**	**$ 49,112**	**$ (158,902)**	**$ 1,243**	**$ 31,185**

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

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

1. Nature of Business and Going Concern

Fennec Pharmaceuticals Inc., a British Columbia corporation ("Fennec," the "Company," "we," "us," or "our"), is a biopharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate) for the prevention of platinum-induced ototoxicity in pediatric cancer patients. We have four wholly-owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian company, and Fennec Pharmaceuticals (EU) Limited ("Fennec Limited"), an Ireland company. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

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

During the three and nine months ended September 30, 2021, the Company incurred a loss from operations of $4,173 and $13,016, respectively. At September 30, 2021, the Company had an accumulated deficit of $175,059 and had experienced negative cash flows from operating activities during the three and nine months ended September 30, 2021 in the amounts of $2,958 and $10,977, respectively.

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

On February 1, 2019, the Company's wholly owned subsidiary Fennec Pharmaceuticals, Inc, entered into a Loan and Security Agreement (the "Bridge Bank Loan and Security Agreement") with Bridge Bank, a division of Western Alliance Bank, an Arizona corporation ("Bridge Bank"), pursuant to which Bridge Bank agreed to loan $12,500 to Fennec Pharmaceuticals, Inc., to be made available upon New Drug Application ("NDA") approval of PEDMARK™ by the U.S. Food and Drug Administration ("FDA") no later than September 30, 2020. The Bridge Bank Loan and Security Agreement was amended on June 26, 2020 to increase the total potential amount of the loan to $18,000 and to extend the outside date to receive NDA approval of PEDMARK™ to December 31, 2020. In connection with this facility, the Company issued Bridge Bank a warrant to purchase up to 39 of the Company's common shares at an exercise price of $6.80 per share, with an exercise period of ten years from the date of issuance subject to certain early termination conditions. Under Accounting Standards Codification ("ASC") 470-50, Modifications and Extinguishments, the amendment to the facility 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 receipt of the FDA's Complete Response Letter ("CRL") in August 2020, which identified deficiencies in the third-party manufacturing facility that manufactures PEDMARK™ on the Company's behalf, the Company decided to fully amortize the remaining portions of the loan fee and the value of the warrants. The warrant issued to Bridge Bank remains outstanding.

On June 24, 2021, the Company announced it had negotiated a second amendment to the Bridge Bank Loan and Security Agreement. This amendment provides Fennec with a $20,000 debt facility comprised of three term loans. Term Loan A consists of $5,000, which was funded upon closing. Term Loan B consists of $7,500 to be funded upon NDA approval of PEDMARK™ in the U.S. Term Loan C consists of $7,500 to be funded upon the Company achieving consolidated trailing six-month revenues of $11 million on or before December 31, 2022. 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 B, provided that Term Loan C is funded, and certain conditions are met. The Company intends to use the proceeds from the loans to provide working capital for commercial readiness activities prior to NDA approval as well as commercialization activities for PEDMARK™, if approved by the FDA.

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

The Company believes the funds raised in its May 2020 public offering, along with the funds from the Bridge Bank Loan and Security Agreement, provide sufficient funding for the Company to carry out its planned activities, including, if PEDMARK™ is approved by the FDA, the commencement of commercialization efforts, for at least the next twelve months as it continues its strategic development of PEDMARK™.

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 U.S. GAAP and are the responsibility of the Company's management. These unaudited interim condensed consolidated financial statements do not include all of the information and notes required by U.S. GAAP for annual financial statements. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes filed with the Securities and Exchange Commission ("SEC") in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. 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, 2020. 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 U.S. GAAP requires management to make estimates and assumptions that impact the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the interim condensed consolidated financial statements and the reported amounts of expense during the reporting period. Actual results could differ from those estimates.

In the opinion of management, these unaudited interim condensed consolidated financial statements include all adjustments, which are normal and recurring in nature, necessary for the fair presentation of the Company's financial position at September 30, 2021 and to state fairly the results for the periods presented. The most significant estimates utilized during the three and nine months ended September 30, 2021 include estimates necessary to value grants of stock options to employees and various contractors, as disclosed in Note 4.

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

New accounting pronouncements

In January 2021, the FASB issued ASU No. 2021-01, Reference Rate Reform (Topic 848). In this ASU, the FASB refines the scope of Topic 848 to clarify that certain optional expedients and exceptions therein for contract modifications and hedge accounting apply to contracts that are affected by the discounting transition. Specifically, modifications related to reference rate reform would not be considered an event that requires reassessment of previous accounting conclusions. The ASU also amends the expedients and exceptions in Topic 848 to capture the incremental consequences of the scope clarification and to tailor the existing guidance to derivative instruments affected by the discounting transition. The amendments in the ASU are effective immediately for all entities. Entities may choose to apply the amendments retrospectively as of any date from the beginning of an interim period that includes or is subsequent to March 12, 2020, or prospectively to new modifications from any date within an interim period that includes or is subsequent to January 7, 2021, up to the date that financial statements are available to be issued. The Company chose to apply amendments prospectively and concluded after evaluation that ASU 2021-01 has no significant effect on its condensed consolidated 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, 2021, the Company had $24,335 in cash, savings and money market accounts ($30,344 at December 31, 2020). At September 30, 2021, the Company held $428 in cash of which $37 (as presented in U.S. dollars) was in Canadian dollars ($45 at December 31, 2020 as presented in U.S. dollars). At September 30, 2021, the Company held $23,907 in money market investments. Money market investments typically have minimal risks. While the Company has not experienced any loss or write-down of its money market investments, the amounts it holds in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

Financial instruments

Financial instruments recognized on the balance sheets at September 30, 2021 and December 31, 2020 consist of cash and cash equivalents, accounts payable, accrued liabilities and long term debt, the carrying values of which approximate fair value due to their relatively short time to maturity. The Company does not hold or issue financial instruments for trading.

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

The policy risks are primarily the opportunity cost of the conservative nature of the allowable investments. As the main purpose of the Company is research and development, the Company has chosen to avoid investments of a trading or speculative nature.

Revenue

The Company’s nominal historical revenue has been generated through sales of its intellectual property (“IP”). For the periods presented, there is no revenue. For periods when the Company has generated its revenue through one segment and the revenue recognized under each of the Company’s arrangements during those periods is described below. The terms of these agreements may contain multiple promised goods or services or optional goods and services, including licenses to product candidates, referred to as exclusive licenses, as well as research and development activities to be performed by the Company on behalf of the collaboration partner related to the licensed product candidates.

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

Revenue recognition

Revenue is recognized when control of the promised goods or services are transferred to customers in an amount that reflects the consideration the Company expects to be entitled to in exchange for transferring those goods or providing services. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable.

When determining whether the customer has obtained control of the goods or services, the Company considers the point at which the customer may benefit from the goods or services. For sale of IP, revenue is recognized upon grant or transfer of the IP, as the Company's IP is considered functional in nature.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The Company's contracts may contain multiple performance obligations if a promise to transfer goods or services is separately identifiable from other promises in a contract and, therefore, is considered distinct. For contracts with multiple performance obligations, the Company determines the standalone selling price of each performance obligation and allocates the total transaction price using the relative selling price basis. The Company recognizes performance obligations based on their nature.

Significant payment terms

The Company's revenue arrangements may include payments to the Company of one or more of the following: a non-refundable, upfront payment; milestone payments; and royalties on commercial sales of IP product candidates, if any. To date, the Company has received upfront payments and several milestone payments but has not received any license or option fees or earned royalty revenue as a result of product sales.

The Company estimates the amount of consideration to which it will be entitled in exchange for satisfying performance obligations. Based on the Company's current contracts, variable consideration primarily exists in the following forms: development and regulatory milestones, royalties and sales-based milestones. The Company utilizes the "most likely amount" variable consideration method for estimating development and regulatory milestone consideration to include in the transaction price. The Company only includes an amount of variable consideration in the transaction price to the extent it is probable that a significant reversal in the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company refers to this as the variable consideration constraint.

Due to the uncertainty associated with the occurrence of any underlying events which would trigger development and regulatory milestone consideration under its revenue arrangements, with the exception of certain initial conditions precedent milestones, the Company has concluded the variable consideration associated with all development and regulatory milestones to be fully constrained as of September 30, 2021, and therefore has not included such consideration in the transaction price for any of its revenue arrangements. The Company will reassess this conclusion at each subsequent reporting period and will only include amounts associated with regulatory or development milestones in the transaction price when, or if, the variable consideration is determined to be released from the constraint.

The Company adjusts the transaction price for the effects of the time value of money if the timing of payments agreed to by the parties to the contract, explicitly or implicitly, provides the Company or its customer with a significant benefit of financing the transfer of goods or services. In relation to the royalties from the sale of Eniluracil to Elion (described under "Revenue arrangements" below), the Company concluded that its licensing and collaboration arrangements do not contain

(U.S. dollars and shares in thousands, except per share information)

a significant financing component because the payment structure of its agreements arise from reasons other than providing a significant benefit of financing.

Contract assets

The Company did not have any contract assets as of September 30, 2021 or December 31, 2020.

Contract liabilities

The Company did not have any contract liabilities as of September 30, 2021 or December 31, 2020.

Revenue arrangements

Elion

In May 2016, the Company sold Eniluracil to Elion Oncology, LLC ("Elion"). The agreement called for $40 in cash and 5% royalties to be paid to Fennec for any income derived from the sale of Eniluracil. The agreement was for the sale (not the license) of IP. In addition, the agreement did not call for any additional good or service beyond the transfer of IP and related assets (e.g. "all information and know-how", documentation, etc.).

In August 2020, Elion entered into a license agreement with Processa Pharmaceuticals, Inc. ("Processa"). The license agreement called for equity and cash upon satisfying the Condition Precedent, along with development and regulatory milestone payments, sales milestone payments, and product royalties. The grant of the license was conditioned upon the "Condition Precedent" which was defined as (i) Processa's closing of a public offering by October 30, 2020 in which Processa raised at least $15,000 and (ii) Processa's shares being listed on NASDAQ. Upon satisfying the Condition Precedent, which occurred in October 2020, Elion was entitled to receive $100 in cash and 825 in shares of Processa of which the Company is entitled to 5%. As a result, in January 2021, the Company received $5 in cash and 41 restricted shares of Processa common shares. The event which triggered the receipt of cash and shares occurred in October of 2020. The revenue for this event was recognized in the fourth quarter ended December 31, 2020.

The agreement between Elion and Processa entitles Elion to the payments outlined in the table below. Fennec would be eligible to receive 5% of the following based on future milestone events:

Milestone Event	Milestone Payment ($)
1st Year Anniversary of Effective Date	100 Restricted Shares
2nd Year Anniversary of Effective Date	100 Restricted Shares
1st Patient in Dose Confirmation Study	100 Restricted Shares
NDA Submission	300 Restricted Shares
1st FDA Approval in US	$ 5,000
2nd FDA Approval in US	$ 3,000
1st Regulatory Approval Outside US	$ 2,000
2nd Regulatory Approval Outside US	$ 2,000

Since the Condition Precedent was achieved, and only the passage of time must occur in order for the 1st and 2nd Year Anniversary payments to become due, the Company concluded the 1st and 2nd Year Anniversary milestone payments are also probable of coming to fruition and thus were included in the transaction price during the fourth quarter ended December 31, 2020 along with the aforementioned Condition Precedent payments.

The arrangement with Elion contains consideration that is variable based on the Processa's achievement of the above referenced development and regulatory milestones. The next milestone payment the Company may be entitled to receive is 5 restricted shares for 1st patient in Dose Confirmation Study and then another 15 restricted shares for the NDA

(U.S. dollars and shares in thousands, except per share information)

submission. These are considered variable consideration that is fully constrained due to the uncertainty associated with the achievement of the development milestone. The considerations related to royalties (first and second FDA approval in U.S. and first and second regulatory approval outside U.S.) are also variable consideration that are fully constrained in accordance with the royalty recognition constraint. The variable consideration related to royalties will be recognized in the period the products are sold by Processa and the Company has a present right to payment.

The Company recognized $200 in revenue associated with the aforementioned cash and shares it became entitled to for the year ended December 31, 2020. Due to the one year lockup provision on the Processa shares, the Company deemed it reasonable to apply a liquidity discount of 20% to the valuation of the shares associated with the achievement of the Condition Precedent. Shares associated with the one- and two-year anniversary milestones had a 30% and 40% liquidity discount applied to their fair market valuations. Recognizing the passage of time, the Company adjusted its liquidity discount to the original shares of 5% and then 20% and 25% for the one- and two-year anniversary tranches.

Subsequent changes to the fair value of the underlying securities are recognized as unrealized gains or losses on marketable equity securities within the condensed consolidated statement of operations. During the quarter ended September 30, 2021, the Company reported $39 in unrealized gain on the fair value of the underlying Processa shares. There is a total unrealized gain on the Processa shares of $137 for the nine months ended September 30, 2021.

3. Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (4,185)	$ (6,200)	$ (12,919)	$ (14,871)
Denominator:				
Weighted-average common shares, basic	26,007	25,598	26,004	22,969
Dilutive effect of stock options	—	—	—	—
Dilutive effect of warrants	—	—	—	—
Incremental dilutive shares	—	—	—	—
Weighted-average common shares, diluted	26,007	25,598	26,004	22,969
Net loss per share, basic and diluted	**$** (0.16)	**$** (0.24)	**$** (0.50)	**$** (0.64)

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options to purchase common shares	3,653	3,095	3,653	3,095
Warrants to purchase common shares	39	39	39	39

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

4. Stockholders' Equity

Authorized capital stock

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

Warrants to Purchase Common Stock

During the three and nine-months ended September 30, 2021 and 2020, there were no warrants issued or exercised. Outstanding warrants have a weighted average life of 7.35 years on September 30, 2021. The following tables detail the Company's warrant activity for the three and nine months ended September 30, 2021 and 2020, respectively:

Investor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price $USD
Outstanding December 31, 2020	39	6.80
Issued	—	—
Outstanding March 31, 2021	39	6.80
Issued	—	—
Outstanding June 30, 2021	39	6.80
Issued	—	—
Outstanding September 30, 2021	**39**	**6.80**

Investor Warrants	Common Shares Issuable Upon Exercise of Outstanding Warrants	Weighted-Average Exercise Price $USD
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**

Stock option plan

Equity Incentive Plan

The Compensation Committee of the Board of Directors administers the Company's equity incentive plan (the "Plan"). The Compensation Committee designates eligible participants to be included under the Plan and approves the number of equity instruments to be granted from time to time under the Plan. Currently, the maximum number of equity instruments issuable under the Plan, together with the Company's prior stock option plan, is twenty-five percent (25%) of the total number of issued and outstanding common shares. Based upon the current shares outstanding, a maximum of 6,502 shares of common stock are authorized for issuance pursuant to stock options or other equity awards granted under the Plan. For all options issued under the Plan, the exercise price is the fair value of the underlying shares on the date of grant. All options vest within three years or less and are exercisable for a period of ten years from the date of grant. The Plan allows

(U.S. dollars and shares in thousands, except per share information)

the issuance of Canadian and U.S. dollar grants. The table below outlines recognized contractor and employee expense from equity awards for the three and nine months period ended September 30, 2021 and 2020.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Contractor options expense recognized	$ —	$ 21	$ 9	$ 63
Employee options expense recognized	917	1,238	2,830	2,151
Total option expense recognized	**$ 917**	**$ 1,259**	**$ 2,839**	**$ 2,214**

Stock option activity

The following is a summary of option activity for the three and nine months ended September 30, 2021, and 2020 for stock options denominated in U.S. dollars. Since August of 2020, there have been no Canadian denominated options outstanding.

US Denominated Options	Number of Options (thousands)	Weighted-Average Exercise Price $USD
Outstanding at December 31, 2020	2,952	$ 4.82
Granted	—	—
Exercised	—	—
Outstanding at March 31, 2021	2,952	$ 4.82
Granted	755	7.52
Exercised	(4)	5.91
Forfeited	(50)	8.09
Outstanding and exercisable at June 30, 2021	3,653	$ 5.34
Granted	—	—
Exercised	—	—
Outstanding at September 30, 2021	**3,653**	**$ 5.34**

During the three-month period ended September 30, 2021, there were no grants or exercises of U.S. denominated options. Of the 3,653 U.S. denominated options granted and outstanding at September 30, 2021, 2,586 are fully vested and exercisable.

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

CAD Denominated Options	Number of Options (thousands)	Weighted-Average Exercise Price $USD
Outstanding at December 31, 2019	648	$ 2.43
Granted	—	—
Exercised	—	—
Outstanding at March 31, 2020	648	$ 2.43
Granted	—	—
Exercised	—	—
Outstanding and exercisable at June 30, 2020	648	$ 2.43
Granted	—	—
Exercised	(648)	2.43
Outstanding at September 30, 2020	**—**	**$ —**

The value of options 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.

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Black-Scholes Model Assumptions	Valuation Assumptions June 30, 2021
Expected dividend	0.00%
Risk free rate	1.49 - 1.62%
Expected volatility	122%
Expected life	10 years

Restricted Share Units Activity

The Plan allows for the issuance of restricted share units ("RSU's"). The following is a summary of RSU activity for the three and nine months ended September 30, 2021, for RSU's denominated in U.S. dollars. Prior to June 2021, there was no activity involving RSU's. Of the 55 RSU's granted and outstanding, 0 are vested. All RSU's vest over three years with 1/3 vesting on the first anniversary date of the grant and then 1/24 on the last day of each subsequent month.

US Denominated RSU's	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2020	—
Granted	—
Outstanding at March 31, 2021	—
Granted	55
Outstanding at June 30, 2021	55
Granted	—
Outstanding at September 30, 2021	**55**

The value of RSU's issued was estimated using the share price on the date of the grant multiplied by the number of shares granted. The Company then applies a liquidity discount to the value to recognize the passage of time over the vesting period.

5. Fair Value Measurements

The Company has adopted ASC 820 the Fair Value Measurements and Disclosure Topic of the FASB. This Topic applies to certain assets and liabilities that are being measured and reported on a fair value basis. The Fair Value Measurements Topic defines fair value, establishes a framework for measuring fair value in accordance with U.S. GAAP, and expands disclosure about fair value measurements. This Topic enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. The Topic requires that financial assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

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

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	Fair Value Measurement at September 30, 2021 and December 31, 2020 (in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2021	2020	2021	2020	2021	2020	2021	2020
Assets								
Cash and cash equivalents	428 (1)	678 (1)	23,907	29,666	—	—	24,335	30,344
Processa common shares	—	—	402 (2)	265 (2)	—	—	402	265

(1) The Company held approximately $428 in cash as of September 30, 2021, of which approximately $37 was in Canadian funds (translated into U.S. dollars). As of December 31, 2020, the Company held approximately $678 in cash of which approximately $45 was in Canadian funds (translated into U.S. dollars).

(2) The Company received 41 restricted common shares of Processa (NASDAQ:PCSA). The share restriction will expire in three tranches: 50%, 25% and 25% at the 6, 9 and 12 month intervals, respectively from October 30, 2020. At October 30, 2020, Processa shares were trading at $4.11 per share. The Company originally applied a 20%, 30% and 40% liquidity discount to the shares and will mark to market at each balance sheet date.

6. Commitments and Contingencies

Oregon Health & Science University Agreement

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

On May 18, 2015, Fennec negotiated an amendment ("Amendment 1") to the OHSU Agreement, which expands Fennec's exclusive license to include the use of N-acetylcysteine as a standalone therapy and/or in combination with sodium thiosulfate for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments 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.

Securities Class Action Suit

Following the FDA's CRL regarding our NDA for PEDMARK™ as described in Note 1, a putative lawsuit was filed against us purportedly on behalf of purchasers of the Company's securities between December 20, 2018 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 its 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.

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Executive Severance

In the event of his termination with us other than for cause, we will be obligated to pay Mr. Raykov a one-time severance payment equal to twelve months of salary ($442 as of September 30, 2021). In the event of his termination with us other than for cause, we will be obligated to pay Mr. Andrade a one-time severance payment equal to six months of salary ($160 as of September 30, 2021). 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 six months of salary ($184 as of September 30, 2021).

Leases

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

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

COVID-19

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

7. Term Loans

On June 24, 2021, the Company announced it had negotiated a second amendment to the Bridge Bank Loan and Security Agreement with Bridge Bank. This amendment provides Fennec with a $20,000 debt facility comprised of three term loans. Term Loan A consists of $5,000, which was funded upon closing. Term Loan B consists of $7,500 to be funded upon NDA approval of PEDMARK™ in the U.S. Term Loan C consists of $7,500 million to be funded upon the occurrence the Company achieving consolidated trailing six-month revenues of $11,000 on or before December 31, 2022. 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 B, provided that Term Loan C is funded, and certain conditions are met. The Company intends to use the proceeds from the loans to provide working capital for commercial readiness activities prior to NDA approval as well as commercialization activities for PEDMARK™, if approved by the FDA.

On June 24, 2021, the Company drew $5,000 from Term Loan A. Term Loan A matures on July 1, 2025. Payments are for interest only through February 1, 2023. The Company shall make equal monthly payments of principal, together with applicable interest, following the interest only period until the maturity date. Interest shall accrue on the outstanding balance at a rate of 1% above prime as published by the Wall Street Journal on the first day of each month. The Company is obligated to maintain a cash balance greater or equal to three times its monthly cash burn as calculated on the last date of the immediately preceding month.

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Aggregate annual payments due on Term Loan A as of September 30, 2021 are as follows (in thousands):

Years Ending December 31,	Amount
2021	$ —
2022	—
2023	1,833
2024	2,000
2025	1,167
Total future payments	5,000
Less: unamortized debt discount	(13)
Total term loan, net of debt discount	$ 4,987

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

Debt issuance costs amounting to $55 securing access to Term Loans A, B and C were paid in cash to Bridge Bank on June 24, 2021. This amount was capitalized and is being amortized over the access period of the Term Loans. Upon drawing Term Loan A, the Company recorded a debt discount of $14, reducing the capitalized amount by the same amount. The debt discount is being amortized over the life of Term Loan A.

8. Subsequent Events

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

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

CAUTIONARY STATEMENT

This section and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements can be identified by words such as “future,” “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “predicts,” “will,” “would,” “could,” “can,” “may,” and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A of the our Annual Report on Form 10-K for the year ended December 31, 2020 under the heading “Risk Factors.” We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2020 and the condensed consolidated financial statements and accompanying notes included elsewhere in this report.

Overview

Product Candidate PEDMARK™

Our only product candidate in the clinical stage of development is:

- PEDMARK™ (a unique formulation of sodium thiosulfate (STS)) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to <18 years of age with localized, non-metastatic, solid tumors. We have 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 in collaboration with the Children’s Oncology Group (“COG ACCL0431”) “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 our resources on the development of PEDMARK™.

We have licensed from Oregon Health and Science University (“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. In addition, adults undergoing chemotherapy for several common malignancies, including ovarian cancer, testicular cancer, and particularly head and neck cancer and brain cancer, often receive intensive platinum-based therapy and may experience severe, irreversible hearing loss, particularly in the high frequencies.

In the U.S. and Europe, it is estimated that, annually, over 10,000 children may receive platinum-based chemotherapy. The incidence of ototoxicity depends upon the dose and duration of chemotherapy, 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.

In March 2018, PEDMARK™ received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration ("FDA"). Further, PEDMARK™ has received Orphan Drug Designation in the U.S. in this setting.

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 with the FDA in December 2018. We announced that we had submitted full completion of the NDA in February 2020. On April 13, 2020, we announced that the FDA had accepted for filing and granted Priority Review for our NDA. 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, we announced that we received a Complete Response Letter ("CRL") from the FDA regarding our NDA for PEDMARK™, which identified deficiencies in the third-party manufacturing facility that manufactures PEDMARK™ on our behalf. Importantly, no clinical safety or efficacy issues were identified during the review and there is no requirement for further clinical data. In the fourth quarter of 2020, we engaged in a Type A meeting with the FDA concerning the CRL that we believe was constructive and collaborative. In May 2021, we announced the resubmission of our NDA for PEDMARK™ and in June 2021 we further announced that the FDA accepted for filing the resubmission of our NDA and set a PDUFA target action date of November 27, 2021.

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 otoxicity induced by cisplatin chemotherapy patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors.

Clinical Studies

PEDMARK™ has been studied by cooperative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, COG ACCL0431 and SIOPEL 6. Both studies have been completed. The COG ACCL0431 protocol enrolled 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.

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 STS 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 conducted and funded all clinical activities and we provided 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 were:

- To assess the efficacy of STS 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:

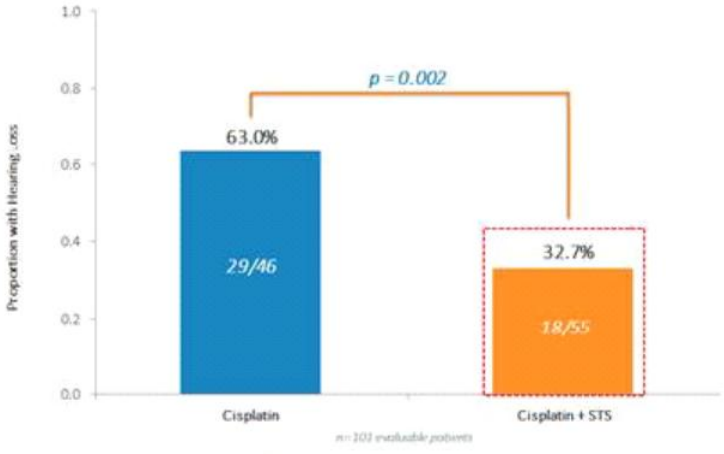
Bilateral high-frequency hearing loss is a serious permanent side-effect of cisplatin therapy, particularly debilitating when occurring in young children. STS has been shown to reduce cisplatin induced hearing loss. SIOPEL 6 was a Phase 3 randomized trial to assess the efficacy of STS in reducing ototoxicity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

Design / Methods:

Newly diagnosed patients with SR-HB, defined as tumor 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+STS for 4 preoperative and 2 postoperative courses. Cisplatin 80mg/m2 was administered over 6 hours, STS 20g/m2 was administered intravenously over 15 minutes exactly 6 hours after stopping cisplatin. Tumor response was assessed after 2 and 4 preoperative cycles with serum AFP and liver imaging. In case of progressive disease (PD), STS was to be stopped and doxorubicin 60mg/m2 combined with cisplatin. The primary endpoint was centrally reviewed absolute hearing threshold, at the age of ≥3.5 years by pure tone audiometry.

Results:

109 randomized patients (52 Cisplatin only ("Cis") and 57 Cis+STS) were evaluable. The combination of Cis+STS was generally well tolerated. With a patient follow-up time of 52 months, the three-year Event Free Survival ("EFS") for Cis was 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=32.7% 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 STS shows that the addition of STS 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 STS to prevent hearing loss in children receiving cisplatin-based chemotherapy in collaboration with the Children's Oncology Group. The goal of this Phase 3 study was to evaluate in a multi-centered, randomized trial whether STS 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, were to receive cisplatin according to their disease-specific regimen and, upon enrollment in this study, were randomized to receive STS or not. Efficacy of STS was determined through comparison of hearing sensitivity at follow-up relative to baseline measurements using standard audiometric techniques. The Children's Oncology Group was responsible for funding the clinical activities for the study and we were 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 125 were eligible patients. The patients had been previously diagnosed with childhood cancers.

The primary endpoint was to evaluate the efficacy of STS 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.

125 eligible subjects were enrolled with germ cell tumor (32), osteosarcoma (29), 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 STS 16 grams/m2 IV over 15 minutes, 6 hours after each cisplatin dose. Hearing was measured using standard audiometry for age and data was 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 STS 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: STS vs. Control was 21.4% (3/14) vs. 73.3% (11/15), respectively (p=0.005).

Conclusions:

- STS 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 $12.9 million for the nine months ended September 30, 2021, and a net loss of $14.9 million for the nine months ended September 30, 2020. As of September 30, 2021, our accumulated deficit was approximately $175.1 million ($162.1 million at December 31, 2020).

We believe that our cash and cash equivalents as of September 30, 2021, which totaled $24.3 million, plus the Bridge Bank Loan and Security Agreement, will be sufficient to meet our cash requirements through at least the next twelve months, including anticipated NDA approval and, if approved, the first commercial launch of PEDMARK™ in the United States. Our projections of our capital requirements are subject to substantial uncertainty, and more capital than we currently anticipate may be required thereafter. To finance our continuing operations, we may need to raise substantial additional funds through either the sale of additional equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out-license or sale of certain aspects of our intellectual property portfolio or from other sources. We may not be able to raise the necessary capital, or such funding may not be available on financially acceptable terms if at all. If we cannot obtain adequate funding in the future, we might be required to further delay, scale back or eliminate certain research and development studies, consider business combinations, or even shut down some, or all, of our operations.

Our operating expenses will depend on many factors, including the progress of our 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, 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, 2021 versus three months ended September 30, 2020:

In thousands of U.S. Dollars	Three Months Ended September 30, 2021	%	Three Months Ended September 30, 2020	%	Change
Revenue	$ —		$ —		$ —
Operating expenses:					
Research and development	1,242	30 %	1,368	23 %	(126)
General and administration	2,931	70 %	4,491	77 %	(1,560)
Total operating expense	4,173	100 %	5,859	100 %	(1,686)
Loss from operations	(4,173)		(5,859)		1,686
Unrealized gain on securities	39		—		39
Amortization expense	(8)		(355)		347
Other losses	(56)		(8)		(48)
Interest income and other, net	13		22		(9)
Net loss	$ (4,185)		$ (6,200)		$ 2,015

Research and development expenses decreased by $126 for the three months ended September 30, 2021 compared to the same period in 2020 as the Company's development activities shifted back to product launch readiness and pre-commercial development of PEDMARK™. General and administrative expenses decreased by $1,560 compared to same period in 2020 due to the timing to NDA approval of the comparative periods. The three months ended September 30, 2020 was the

same quarter as the initial NDA approval and the three months ended September 30, 2021 is one quarter prior to our current potential NDA approval. The reduction in general and administrative expenses was slightly offset by higher expenses associated with additional employees.

The Company holds shares of Processa (NASDAQ: PCSA), which are marked to market each balance sheet date and unrealized gains or losses are recognized at that time. The unrealized gain on those shares for the three months ended on September 30, 2021, was $39. Other losses were driven mainly by interest expense and unrealized losses related to the Company's foreign currency transactions. The Company has vendors that transact in Euros, Great British Pounds and Canadian Dollars. There was an increase of $48 in other losses for the three months ended September 30, 2021, compared to the same period in 2020. 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 decreased by $347 for the three months ended September 30, 2021 compared to the same period in 2020. In 2021, the Company is amortizing the capitalized costs associated with the renegotiated Bridge Bank loan facility. During the same period in 2020, the Company wrote off the remaining capitalized cost associated with the former facility after it received the CRL from the FDA in August 2020. Interest income was $9 lower for the three months ended September 30, 2021, compared to the same period in 2020. This was driven by lower average cash balance for the three months ended September 30, 2021 compared to the same period in 2020.

Nine months ended September 30, 2021 versus nine months ended September 30, 2020:

In thousands of U.S. Dollars	Nine Months Ended September 30, 2021	%	Nine Months Ended September 30, 2020	%	Change
Revenue	$ —		$ —		$ —
Operating expenses:					
Research and development	4,458	34 %	3,882	27 %	576
General and administration	8,558	66 %	10,657	73 %	(2,099)
Total operating expenses	13,016	100 %	14,539	100 %	(1,523)
Loss from operations	(13,016)		(14,539)		1,523
Unrealized gain on securities	137		—		137
Other losses	(73)		(4)		(69)
Amortization expense	(8)		(402)		394
Interest income	41		74		(33)
Net loss	$ (12,919)		$ (14,871)		$ 1,952

Research and development expenses increased by $576 for the nine months ended September 30, 2021, compared to the same period in 2020. The Company's research and development activities for the first nine months of 2021 increased as the Company prepared for the NDA resubmission. General and administrative expenses decreased by $2,099 over same period in 2020 as expenses associated with pre-commercialization activities decreased on a year over year basis. This relates to the planned timing and the fact that many pre-commercialization activities were performed in 2020.

The Company holds shares of Processa (NASDAQ: PCSA) which are marked to market each balance sheet date and unrealized gains or losses are recognized at that time. The unrealized gain on those shares for the nine months ended on September 30, 2021 was $137. Other losses were driven mainly by interest expense and unrealized losses related to the Company's foreign currency transactions. The Company has vendors that transact in Euros, Great British Pounds and Canadian Dollars. There was an increase of $69 in other losses for the nine months ended September 30, 2021, compared to the same period in 2020. Amortization expense is also a non-cash expense and relates to amortization of the deferred issuance cost of the loan facilities with Bridge Bank. Amortization expense decreased by $394 for the nine months ended September 30, 2021 compared to the same period in 2020. In 2021, the Company is amortizing the capitalized costs associated with the renegotiated Bridge Bank loan facility. During the same period in 2020, the Company wrote off the remaining capitalized cost associated with the former facility after it received the CRL from the FDA in August 2020. Interest income was $33 lower for the nine months ended September 30, 2021, compared to the same period in 2020. This was driven mainly by a sharp decrease in interest rates and lower average cash balance for the nine months ended September 30, 2021 compared to the same period in 2020.

Quarterly Information

The following table presents selected condensed financial data for each of the last eight quarters through September 30, 2021, as prepared under U.S. 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, 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)
December 31, 2020	(3,238)	(0.13)	(0.13)
March 31, 2021	(4,733)	(0.18)	(0.18)
June 30, 2021	(4,001)	(0.15)	(0.15)
September 30, 2021	(4,185)	(0.16)	(0.16)

Liquidity and Capital Resources

Selected Asset and Liability Data (thousands):	As at September 30, 2021	As at December 31, 2020
Cash and equivalents	$ 24,335	$ 30,344
Other current assets	1,644	1,073
Current liabilities	2,014	2,347
Working capital [(1)]	23,965	29,070
[(1)] [Current assets – current liabilities]		
Selected Equity:		
Common stock and additional paid in capital	192,829	189,967
Accumulated deficit	(175,059)	(162,140)
Shareholders' equity	19,013	29,070

Cash and cash equivalents were $24,335 at September 30, 2021 and $30,344 at December 31, 2020. The decrease in cash and cash equivalents between September 30, 2021, and December 31, 2020 is the result of expenses related to the development and preparation of the NDA resubmission of PEDMARK™ and general and administrative expenses, which was offset by a draw of $5,000 from the Bridge Bank Loan and Security Agreement. There was an increase of $571 in other current assets between September 30, 2021 and December 31, 2020. This is a result of a $242 increase in deferred charges related to the financing of the director and officer's insurance policy, a $137 increase in the value of Processa shares and an increase in prepaid expenses of $192.

Current liabilities decreased primarily due to the reduction in manufacturing and regulatory expenses associated with the PEDMARK™ NDA resubmission.

Working capital decreased between December 31, 2020 and September 30, 2021 by $5,105. The decrease relates to cash expenditures for operating activities for the nine months ended September 30, 2021, offset by the $5,000 draw from the Bridge Bank Loan and Security Agreement. The Company expects increases in cash outflows related to pre commercialization and commercialization activities in the coming quarters upon potential NDA approval.

The following table illustrates a summary of cash flow data for the three and nine-month periods of September 30, 2021 and 2020:

Selected Cash Flow Data (dollars and shares in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net cash used in operating activities	$ (2,958)	$ (5,446)	$ (10,977)	$ (12,311)
Net cash provided by investing activities	—	—	—	—
Net cash (used in)/provided by financing activities	—	(117)	4,968	31,827
Net cash flow	$ (2,958)	$ (5,563)	$ (6,009)	$ 19,516

Net cash used in operating activities for the three and nine months ended September 30, 2021 primarily reflected a net loss of $4,185 and $12,919, respectively. These three- and nine-month losses were adjusted for the add back of non-cash items consisting of $917 and $2,839, respectively, in stock-based compensation expense, with unrealized gains on securities of $39 and $137 added back for the three and nine months ended September 30, 2021, respectively. For the three and nine months ended September 30, 2021, there was a net change in prepaid and other assets of $824 and $434, respectively; coupled with a net increase in current liabilities of $1,166 for the three months ended September 30, 2021, and a net decrease of $333 for the nine months ended September 30, 2021. Three- and nine-month cash flows from operating activities were negative $2,958 and $10,977, respectively, for the period ended September 30, 2021. Net cash provided by financing activities for the three and nine months ended September 30, 2021 was $0 and $4,968, respectively. Financing activities consisted of $5,000 gross proceeds from the Bridge Bank Loan Security Agreement, $24 from the exercise of options, netted against $56 in capitalized deferred loan costs. Net cash flows from the three and nine month period ended September 30, 2021 were negative $2,958 and $6,009, respectively.

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

Our outstanding share data as of September 30, 2021 and December 31, 2020 was as follows (in thousands):

Outstanding Share Type	September 30, 2021	December 31, 2020	Change
Common shares	26,007	26,003	4
Warrants	39	39	—
Stock options	3,653	2,952	701
Total	29,699	28,994	705

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, 2021, we had approximately $428 in our cash accounts and $23,907 in savings and money market accounts. While we have never experienced any loss or write down of our money market investments since our inception, the amounts we hold in money market accounts are substantially above the $250,000 amount insured by the FDIC and may lose value.

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

The policy risks are primarily the opportunity cost of the conservative nature of the allowable investments. As our main purpose is 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™ 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, 2021, and 2020 were $1,242 and $1,368, respectively, and for the nine-months ended September 30, 2021, and 2020 were $4,458 and $3,882, respectively. We have decreased our research and development expenses related to PEDMARK™ as our efforts have shifted to pre-commercialization activities after the NDA resubmission in May 2021.

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 U.S. 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, 2020.

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, 2021, we had $23,907 in money market investments and savings accounts as compared to $29,666 at December 31, 2020; 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. While we have never experienced any loss or write down of our money market investments since our inception, the amounts we hold in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

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

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, 2021, we held approximately $47 Canadian dollars ($37 as presented to U.S. dollars). At December 31, 2020, we held approximately $59 Canadian dollars ($45 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, 2021.

(b) Changes in Internal Control over Financial Reporting

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

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

Chapman v. Fennec Pharmaceuticals Inc.

On September 2, 2020, a putative class action lawsuit, Chapman v. Fennec Pharmaceuticals Inc., was filed against us, our Chief Executive Officer, Rostislav Raykov, and our Chief Financial Officer, Robert Andrade, in the United States District Court for the Middle District of North Carolina. The complaint alleged that prior to our August 10, 2020 receipt of a CRL from the FDA concerning our NDA for PEDMARK™, we made materially false or misleading statements and failed to disclose material facts about the status of our PEDMARK™ manufacturing facility, its compliance with current good manufacturing practices, and the impact its status and compliance would have on regulatory approval for PEDMARK™ . On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our board of directors as defendants, asserts a putative class period from December 10, 2018 through August 10, 2020, makes allegations similar to those in the original complaint, and claims the defendants violated Section 10(b) of the Securities Exchange Act of 1934. On March 3, 2021, we and the other defendants filed a motion to dismiss the amended complaint. On April 2, 2021, plaintiffs filed an opposition to the motion. On April 16, 2021, we and the other defendants filed a reply brief in support of the motion. The court has not scheduled argument or issued an order on the motion.

We believe that the suit is without merit and intend to defend it vigorously. We cannot predict the outcome of this suit. Failure by us to obtain a favorable resolution of the suit could have a material adverse effect on our business, results of operations and financial condition. We have not recorded a liability as of September 30, 2021, because we believe a potential loss is not probable or reasonably estimable given the preliminary nature of the proceedings.

Hope Medical Enterprises, Inc.

On October 29, 2021, Hope Medical Enterprises, Inc. (Hope) filed two (2) petitions for inter partes review (IPR) with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office. In its petitions, Hope seeks to invalidate U.S. Patent No. 10,596,190 (US ‘190), which relates to a method of using our PEDMARK™ product, and U.S. Patent No. 10,792,363 (US ’363), which relates to an anhydrous form of sodium thiosulfate (STS), which is the active pharmaceutical ingredient in our PEDMARK™ product. The US ‘190 was issued on March 24, 2020. The US ‘363 was issued on October 6, 2020. We will have an initial deadline in February 2022, to file preliminary responses to the petitions, if we choose to file responses, and thereafter, the PTAB has three (3) months to decide whether to institute IPR proceedings. If the PTAB institutes one or both reviews, the final written decision(s) will be due about one (1) year after the PTAB’s decision to institute IPR proceedings, and following additional submissions by the parties. Any appeals of a PTAB decision would delay any final outcome.

Fennec plans to vigorously defend our intellectual property rights related to PEDMARK™.

Item 1A. Risk Factors.

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021 (the “Annual Report”), includes a detailed discussion of our risk factors under the heading “PART I, Item 1A – Risk Factors.” You should carefully consider the risk factors discussed in our Annual Report, as well as other information in this quarterly report. Any of these risks could cause our business, financial condition, results of operations and future growth prospects to suffer. We are not aware of any material changes from the risk factors previously disclosed.

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

None

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On November 10, 2021, we issued a press release announcing our financial results for the quarter ended September 30, 2021. A copy of the news release is attached to this report as Exhibit 99.1. The press release is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references the press release.

Item 6. Exhibits

Exhibit No.	Description
31.1	Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
99.1	Press Release for Quarter Ended September 30, 2021 (filed herewith).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

SIGNATURES

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

Fennec Pharmaceuticals Inc.

Date: November 10, 2021

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

Date: November 10, 2021

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

Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Rostislav Raykov, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2021 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 10, 2021

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

Exhibit 31.2

FENNEC PHARMACEUTICALS INC.
CERTIFICATION

I, Robert Andrade, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2021 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 10, 2021

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

Exhibit 32.1

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

In connection with the Quarterly Report of Fennec Pharmaceuticals Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 (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 10, 2021

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

Date: November 10, 2021

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

FENNEC PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2021 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ FDA Prescription Drug User Fee Act (PDUFA) Target Action Date Set for November 27, 2021 ~

~ If Approved by the FDA, PEDMARK™ Stands to Be the First Therapy for the Prevention of Cisplatin-Induced Hearing Loss in Children ~

~ Company Has Approximately $24 Million in Cash and Cash Equivalents ~

Research Triangle Park, NC, November 10, 2021 – 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, 2021 and provided a business update.

"We continue to work with the FDA on their review of our NDA application, in advance of the pending PEDMARK™ PDUFA target action date of November 27th. We are focused on essential activities in preparation to bring this important treatment to children receiving cisplatin chemotherapy," said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals, Inc.

Financial Results for the Third Quarter 2021

- **Cash Position –** Cash and cash equivalents were $24.3 million as of September 30, 2021. The decrease in cash and cash equivalents between September 30, 2021, and June 30, 2020 is the result of expenses related to the development and preparation of the NDA resubmission of PEDMARK™ and general and administrative expenses. As of September 30, 2021, the Company had $5.0 million in funded debt.
- **Research and Development (R&D) Expenses** – R&D expenses were $1.2 million for the third quarter ended September 30, 2021 compared to $1.4 million for the same period in 2020. R&D expenses decreased by $0.2 million for the three months ended September 30, 2021 over the same period in 2020 as the Company's development activities shifted back to essential activities in preparation for the launch of PEDMARK™.
- **General and Administrative (G&A) Expenses –** G&A expenses decreased by $1.6 million over same period in 2020 due to the timing to NDA approval of the comparative periods. The three months ended September 30, 2020 was the same quarter as the initial NDA approval and the three months ended September 30, 2021 is one quarter prior to our current potential NDA approval. The reduction in general and administrative expenses was slightly offset by higher expenses associated with additional employees and the increase in non-cash equity remuneration expense for employees and board members related to the vesting of new and existing grants.

- **Net Loss –** Net loss for the quarter ended September 30, 2021 was $4.2 million ($0.16 per share), compared to $6.2 million ($0.24 per share) for the same period in 2020.

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, 2021 and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

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

	Three Months Ended	
	September 30, 2021	**September 30, 2020**
Revenue	$ —	$ —
Operating expenses:		
Research and development	1,242	1,368
General and administrative	2,931	4,491
Loss from operations	(4,173)	(5,859)
Other (expense)/income		
Unrealized gain on securities	39	—
Amortization expense	(8)	(355)
Other loss	(56)	(8)
Interest income	13	22
Total other income, net	(12)	(341)
Net (loss)	$ (4,185)	$ (6,200)
Basic net (loss) per common share	$ (0.16)	$ (0.24)
Diluted net (loss) per common share	$ (0.16)	$ (0.24)

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 24,335	$ 30,344
Prepaid expenses	1,232	797
Other current assets	412	276
Total current assets	25,979	31,417
Non-Current assets		
Deferred issuance cost	508	466
Deferred issuance cost (amortization)	(473)	(466)
Total non-current assets	35	—
Total assets	$ 26,014	$ 31,417
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,154	$ 1,571
Accrued liabilities	860	776
Total current liabilities	2,014	2,347
Long term liabilities		
Term loan	5,000	—
Debt discount	(13)	—
Total long term liabilities	4,987	—
Total liabilities	7,001	2,347
Shareholders' equity:		
Common stock, no par value; unlimited shares authorized; 26,010 shares issued and outstanding (2020 -26,003)	140,780	140,733
Additional paid-in capital	52,049	49,234
Accumulated deficit	(175,059)	(162,140)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' equity	19,013	29,070
Total liabilities and shareholders' equity	$ 26,014	$ 31,417

Working Capital

Selected Asset and Liability Data:	Fiscal Year Ended September 30, 2021	December 31, 2020
(U.S. Dollars in thousands)		
Cash and cash equivalents	$ 24,335	$ 30,344
Other current assets	1,644	1,073
Current liabilities	(2,014)	(2,347)
Working capital	$ 23,965	$ 29,070
Selected Equity:		
Common stock & APIC	$ 192,829	$ 189,967
Accumulated deficit	(175,059)	(162,140)
Stockholders' equity	19,013	29,070

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 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 FDA has accepted for filing the Company's New Drug Application (NDA) for PEDMARK™ and has granted Priority Review. PEDMARK has received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018, and a Prescription Drug User Fee Act (PDUFA) Target Action Date of November 27, 2021. The Marketing Authorization Application (MAA) for sodium thiosulfate (tradename PEDMARQSI) is currently under evaluation by the European Medicines Agency (EMA).

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

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and

similar expressions, are intended to identify forward-looking statements. These forward-looking statements include the Company's expectations regarding its interactions and communications with the FDA, including the Company's expectations and goals respecting the NDA resubmission for PEDMARK™. Obtaining Fast Track Designation and Breakthrough Therapy Designation by the FDA is no guarantee that the FDA will approve the NDA resubmission of PEDMARK. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risk that unforeseen factors may result in delays in or failure to obtain FDA approval of PEDMARK, the risks and uncertainties relating to the Company's reliance on third party manufacturing, the risks that the Company's NDA resubmission does not adequately address the concerns identified in the CRL previously provided by the FDA, the risk that the NDA resubmission to the FDA will not be satisfactory, that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, 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, 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 and www.sedar.com.

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