

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 March 31, 2024  
OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32295

**FENNEC PHARMACEUTICALS INC.**

(Exact Name of Registrant as Specified in Its Charter)

|  |   |
|--|---|
| British Columbia, Canada<br>(State or Other Jurisdiction of<br>Incorporation or Organization)                              | 20-0442384<br>(I.R.S. Employer<br>Identification No.) |
| PO Box 13628, 68 TW Alexander Drive<br>Research Triangle Park , North Carolina<br>(Address of Principal Executive Offices) | 27709<br>(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 May 10, 2024, there were 27,322,141 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)**

|  | <b>March 31, 2024</b>   | <b>March 31, 2023</b>   |
|--|-------------------------|-------------------------|
|  | <b>(Unaudited)</b>      | <b>(Audited)</b>        |
| <b>Assets</b>  |                         |                         |
| <b>Current assets</b>  |                         |                         |
| Cash and cash equivalents  | \$ 51,184               | \$ 13,269               |
| Accounts receivable, net   | 10,274                  | 8,814                   |
| Prepaid expenses   | 4,488                   | 2,575                   |
| Inventory  | 2,064                   | 2,156                   |
| Other current assets   | 161                     | 44                      |
| <b>Total current assets</b>  | <u>68,171</u>           | <u>26,858</u>           |
| <b>Non-current assets</b>  |                         |                         |
| Other non-current assets, net of amortization  | 1,022                   | 6                       |
| <b>Total non-current assets</b>  | <u>1,022</u>            | <u>6</u>                |
| <b>Total assets</b>  | <u><u>\$ 69,193</u></u> | <u><u>\$ 26,864</u></u> |
| <b>Liabilities and stockholders' equity/(deficit)</b>  |                         |                         |
| <b>Current liabilities:</b>  |                         |                         |
| Accounts payable   | \$ 5,204                | \$ 3,778                |
| Accrued liabilities  | 4,363                   | 3,754                   |
| Operating lease liability - current  | 17                      | 21                      |
| Contract liability - Norgine   | 252                     | —                       |
| <b>Total current liabilities</b>   | <u>9,836</u>            | <u>7,553</u>            |
| <b>Long-term liabilities</b>   |                         |                         |
| Term loan  | 30,000                  | 30,000                  |
| PIK interest   | 1,617                   | 1,219                   |
| Debt discount  | ( 268 )                 | ( 288 )                 |
| Contract liability - long-term   | 24,994                  | 2                       |
| <b>Total long-term liabilities</b>   | <u>56,343</u>           | <u>30,933</u>           |
| <b>Total liabilities</b>   | <u>66,179</u>           | <u>38,486</u>           |
| <b>Commitments and contingencies (Note 6)</b>  |                         |                         |
| <b>Stockholders' equity/(deficit):</b>   |                         |                         |
| Common stock, no par value; unlimited shares authorized; 27,105 shares issued and outstanding (2023 - 27,027 ) | 144,934                 | 144,307                 |
| Additional paid-in capital   | 63,245                  | 62,073                  |
| Accumulated deficit  | ( 206,408 )             | ( 219,245 )             |
| Accumulated other comprehensive income   | 1,243                   | 1,243                   |
| <b>Total stockholders' equity/(deficit)</b>  | <u>3,014</u>            | <u>( 11,622 )</u>       |
| <b>Total liabilities and stockholders' equity/(deficit)</b>  | <u><u>\$ 69,193</u></u> | <u><u>\$ 26,864</u></u> |

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

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

|   | <b>Three Months Ended</b> |                           |
|---|---------------------------|---------------------------|
|   | <b>March 31,<br/>2024</b> | <b>March 31,<br/>2023</b> |
| <b>Revenue</b>  |                           |                           |
| PEDMARK product sales, net  | \$ 7,419                  | \$ 1,677                  |
| Licensing revenue   | 17,958                    | —                         |
| <b>Total revenue</b>  | <u>25,377</u>             | <u>1,677</u>              |
| <br><b>Operating expenses:</b>                                      |                           |                           |
| Cost of product sales   | 550                       | 95                        |
| Research and development  | 3                         | 4                         |
| Selling and marketing   | 5,209                     | 2,531                     |
| General and administrative  | 5,872                     | 4,317                     |
| <br><b>Total operating expenses</b>                                 | <u>11,634</u>             | <u>6,947</u>              |
| <b>Net income/(loss) from operations</b>                            | <u>13,743</u>             | <u>( 5,270 )</u>          |
| <br><b>Other (expense)/income</b>                                   |                           |                           |
| Unrealized foreign exchange (loss)/gain                             | ( 38 )                    | 9                         |
| Amortization expense  | ( 20 )                    | ( 72 )                    |
| Unrealized loss on securities                                       | ( 11 )                    | ( 30 )                    |
| Interest income   | 197                       | 109                       |
| Interest expense  | ( 1,034 )                 | ( 798 )                   |
| Total other expense   | <u>( 906 )</u>            | <u>( 782 )</u>            |
| <br><b>Net income/(loss) from operations</b>                        | <u>\$ 12,837</u>          | <u>\$ ( 6,052 )</u>       |
| <br><b>Basic net income/(loss) per common share</b>                 | <u>\$ 0.47</u>            | <u>\$ ( 0.23 )</u>        |
| <b>Diluted net income/(loss) per common share</b>                   | <u>\$ 0.41</u>            | <u>\$ ( 0.23 )</u>        |
| <b>Weighted-average number of common shares outstanding basic</b>   | <u>27,045</u>             | <u>26,559</u>             |
| <b>Weighted-average number of common shares outstanding diluted</b> | <u>31,091</u>             | <u>26,559</u>             |

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

**Fennec Pharmaceuticals Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity (Deficit)**  
**Three Months Ended March 31, 2024 and 2023**  
(U.S. dollars and shares in thousands)  
(U unaudited)

|                                      | Common Stock  |                   | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Other<br>Comprehensive<br>Income | Total<br>Stockholders'<br>Equity |
|--------------------------------------|---------------|-------------------|----------------------------------|------------------------|----------------------------------|----------------------------------|
|                                      | Shares        | Amount            |                                  |                        |                                  |                                  |
| <b>Balance at December 31, 2023</b>  | 27,027        | \$ 144,307        | \$ 62,073                        | \$( 219,245 )          | \$ 1,243                         | \$ ( 11,622 )                    |
| Stock-based compensation - employees | —             | —                 | 1,191                            | —                      | —                                | 1,191                            |
| Stock option exercise                | 75            | 627               | —                                | —                      | —                                | 627                              |
| Restricted stock release             | 3             | —                 | ( 19 )                           | —                      | —                                | ( 19 )                           |
| Net income                           | —             | —                 | —                                | 12,837                 | —                                | 12,837                           |
| <b>Balance at March 31, 2024</b>     | <b>27,105</b> | <b>\$ 144,934</b> | <b>\$ 63,245</b>                 | <b>\$( 206,408 )</b>   | <b>\$ 1,243</b>                  | <b>\$ 3,014</b>                  |
|                                      | Common Stock  |                   | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Other<br>Comprehensive<br>Income | Total<br>Stockholders'<br>Equity |
|                                      | Shares        | Amount            |                                  |                        |                                  |                                  |
| <b>Balance at December 31, 2022</b>  | 26,361        | \$ 142,591        | \$ 56,797                        | \$( 203,200 )          | \$ 1,243                         | \$ ( 2,569 )                     |
| Stock-based compensation - employees | —             | —                 | 1,089                            | —                      | —                                | 1,089                            |
| Stock option exercise                | 49            | 213               | —                                | —                      | —                                | 213                              |
| Restricted stock release             | 1             | —                 | ( 20 )                           | —                      | —                                | ( 20 )                           |
| Net loss                             | —             | —                 | —                                | ( 6,052 )              | —                                | ( 6,052 )                        |
| <b>Balance at March 31, 2023</b>     | <b>26,411</b> | <b>\$ 142,804</b> | <b>\$ 57,866</b>                 | <b>\$( 209,252 )</b>   | <b>\$ 1,243</b>                  | <b>\$ ( 7,339 )</b>              |

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

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

|  | <b>Three Months Ended</b> |                           |
|--|---------------------------|---------------------------|
|  | <b>March 31,<br/>2024</b> | <b>March 31,<br/>2023</b> |
| <b>Cash flows provided by (used in):</b>   |                           |                           |
| <b>Operating activities:</b>   |                           |                           |
| Net income/(loss)  | \$ 12,837                 | \$ ( 6,052 )              |
| Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities: |                           |                           |
| Amortization of Norgine asset  | 723                       | 52                        |
| Amortization of debt discount  | 16                        | —                         |
| Amortization of debt access fees   | 4                         | 20                        |
| Unrealized loss on securities  | 11                        | 30                        |
| PfK interest   | 398                       | —                         |
| Stock-based compensation - employees   | 1,191                     | 1,089                     |
| Changes in operating assets and liabilities:   |                           |                           |
| Accounts receivable  | ( 1,460 )                 | ( 138 )                   |
| Prepaid expenses   | ( 1,913 )                 | 131                       |
| Inventory  | 92                        | ( 342 )                   |
| Other current assets   | ( 133 )                   | —                         |
| Accounts payable   | 1,426                     | 557                       |
| Accrued liabilities  | 609                       | ( 924 )                   |
| Contract liability - Norgine   | 25,246                    | —                         |
| Net cash provided by/(used in) operating activities  | <u>39,047</u>             | <u>( 5,577 )</u>          |
| <b>Financing activities:</b>   |                           |                           |
| Issuance of shares, options exercise   | 627                       | 213                       |
| Cash paid for taxes on restricted share release  | ( 19 )                    | ( 20 )                    |
| Deferred issuance costs  | <u>( 1,740 )</u>          | —                         |
| Net cash (used in)/provided by financing activities  | <u>( 1,132 )</u>          | <u>193</u>                |
| Increase/(decrease) in cash and cash equivalents   | 37,915                    | ( 5,384 )                 |
| Cash and cash equivalents - Beginning of period  | 13,269                    | 23,774                    |
| Cash and cash equivalents - End of period  | <u>\$ 51,184</u>          | <u>\$ 18,390</u>          |
| <b>Non-cash investing and financing activities:</b>  |                           |                           |
| <b>Supplemental disclosures of cash flow information:</b>  |                           |                           |
| <b>Non-cash investing and financing activities:</b>  |                           |                           |
| Financed insurance policy  | <u>\$ —</u>               | <u>\$ 221</u>             |

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

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

**1. Nature of Business and Liquidity**

Fennec Pharmaceuticals Inc. ("Fennec," "the Company," "we," "us," or "our") was originally formed as a British Columbia corporation under the name Adherex Technologies Inc. and subsequently changed its name on September 3, 2014. Fennec, together with its wholly owned subsidiaries Oxiquant, Inc. ("Oxiquant") and Fennec Pharmaceuticals, Inc., both Delaware corporations, and Cadherin Biomedical Inc. ("CBI"), a Canadian corporation and Fennec Pharmaceuticals (EU) Limited, an Irish Private Company Limited by Shares ("Fennec Limited"), collectively referred to herein as the "Company," is a biopharmaceutical company with one U.S. Food and Drug Administration ("FDA") approved product, PEDMARK®, developed to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. With the exception of Fennec Pharmaceuticals, Inc., and Fennec Limited, all subsidiaries are inactive.

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

During the three months ended March 31, 2024, the Company earned net income from operations of \$ 13,743 . On March 31, 2024, it had an accumulated deficit of \$ 206,408 and had experienced positive cash flows from operating activities in the amount of \$ 39,047 for the period ended March 31, 2024.

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

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

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

A commitment fee of 2.0 % of the Notes was payable under the SPA, which was paid by the Company issuing the Investor warrants to purchase 110,996 of the Company's common shares (one half issued at the first closing and the other half issued at the second closing).The warrants are exercisable at a price per share of \$ 8.11 and have a term of five years from the date of the grant.

On December 4, 2023, the Company closed a third tranche under the SPA in the amount of \$ 5,000,000 and issued the Investor a Note in the same amount (the "Third Closing Note"). and the Third Closing Note is convertible at a price equal to \$ 7.89 per share, calculated as a 20 % premium of the 5 -day volume weighted average price of the Company's common shares as traded on the Nasdaq Capital Market immediately prior to September 20, 2022, which was the date the Company obtained FDA approval of PEDMARK®.

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

On March 17, 2024, the Company announced it had entered into an exclusive licensing agreement with Norgine Pharma UK Limited ("Norgine") to commercialize PEDMARQSI® (EU brand name for PEDMARK®) in Europe, New Zealand and Australia. The licensing agreement provided Fennec with approximately \$ 43.2 million up front and may provide Fennec with up to approximately \$ 230 million in milestone and royalty payments in the future.

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

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, 2023. The Company's accounting policies are consistent with those presented in the audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2023. These unaudited interim condensed consolidated financial statements have been prepared in U.S. dollars. All amounts presented are in thousands except for per share amounts.

### **Use of Estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expense during the reporting period. Significant estimates include revenue recognition, allowance against trade receivables, measurement of stock-based compensation and estimates of the Company's capital requirement over the next twelve months from the date of issuance of the consolidated financial statements. Actual results could differ from those estimates.

### **Segment and Geographic Information**

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

principally in the United States. As of March 31, 2024, the Company had an operating lease in Ireland. This is the only asset located outside of the United States.

#### **Stock-Based Compensation**

Under the Company's stock-based compensation programs, the Company periodically grants stock options and restricted stock to employees, directors and consultants. The Company also issues shares under an employee stock purchase plan. The fair value of each award is recognized in the Company's statements of operations over the requisite service period for such award.

The Company uses the Black-Scholes option pricing model to value stock option awards without market conditions, which requires the Company to make certain assumptions regarding the expected volatility of its common stock price, the expected term of the option grants, the risk-free interest rate and the dividend yield with respect to its common stock. The Company calculates volatility using its historical stock price data. Due to the lack of the Company's own historical data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the Company's stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate used for each grant is based on the United States Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and, at present, has no intention to pay cash dividends.

#### **Inventory**

Inventories are valued under a standard costing methodology on a first-in, first-out basis and are stated at the lower of cost or net realizable value. The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Capitalized costs of inventories mainly include third party manufacturing, logistics and distribution costs. The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories. The manufacturing costs for PEDMARK® prior to regulatory approval were not capitalized as inventory but were expensed as research and development costs. The Company expensed pre-launch inventory as it could not reasonably anticipate FDA approval of PEDMARK®.

#### **Revenue Recognition**

Under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company determines it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation(s). As part of the accounting for these arrangements, the Company must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

#### **License Agreements**

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

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

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

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

### **Costs to Obtain Contract**

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

### **Net Product Revenue**

On September 20, 2022, the FDA approved PEDMARK® in the United States to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. PEDMARK® became commercially available on October 17, 2022. PEDMARK® is the Company's first commercial product. These specialty distributors subsequently resell the Company's products to health care providers and patients. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products. Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the customer.

### **Product Sales Discounts and Allowances**

The Company records revenues from product sales at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established primarily from discounts, chargebacks, rebates, co-pay assistance, returns and other allowances that are offered within contracts between the Company and its Customers, health care providers, payors and other indirect customers relating to the sales of its products. These reserves are based on the amounts to be claimed on the related sales and are classified as a contra-asset or a current liability. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, forecasted customer buying and payment patterns, and the Company's historical experience that will develop over time as PEDMARK® is the Company's first commercial product. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of its contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it

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is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenues and earnings in the period such variances become known.

**Chargebacks:** Chargebacks are discounts that occur when contracted customers purchase directly from a specialty distributor. Contracted customers, which currently consist of Public Health Service institutions and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back to the Company the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by its contracted customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales by the specialty distributor to its contracted customers.

**Discounts for Prompt Payment:** The Customers receive a discount of 0.65 % for prompt payment. The Company expects its Customers will earn 100 % of their prompt payment discounts and, therefore, the Company deducts the full amount of these discounts from total product sales when revenues are recognized.

**Rebates:** Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and other government programs. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. The Company's estimates for the expected utilization of rebates are based on customer and payer data received from the specialty distributors and historical utilization rates that will develop over time as PEDMARK® is the Company's first commercial product. Rebates are generally invoiced by the payor and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to the customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust its accruals, which would affect net product revenues in the period of adjustment.

**Co-payment Assistance:** Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The Company accrues a liability for co-payment assistance based on actual program participation and estimates of program redemption using customer data provided by the third party that administers the copay program.

**Other Customer Credits:** The Company pays fees to its Customers for account management, data management and other administrative services. To the extent the services received are distinct from the sale of products to its Customers, the Company classifies these payments in selling and marketing expenses in its condensed consolidated statements of operations.

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

The following table summarizes net product revenues for PEDMARK® in the United States earned in the three months ended March 31, 2024 and 2023, respectively:

| In thousands             | Three Months Ended |                   |
|--------------------------|--------------------|-------------------|
|                          | March 31,<br>2024  | March 31,<br>2023 |
| Product revenues:        |                    |                   |
| Gross product revenues   | \$ 9,556           | \$ 1,895          |
| Discounts and allowances | ( 2,137 )          | ( 218 )           |
| Net product revenues     | <u>\$ 7,419</u>    | <u>\$ 1,677</u>   |

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For the three months ended March 31, 2024 and 2023, the Company had three distributors that each represented more than 10% of net sales.

The activities and ending allowance balances for each significant category of discounts and allowances for PEDMARK® (which constitute variable consideration) for the three months ended March 31, 2024, was as follows:

| In thousands                                | Chargebacks,<br>Discounts for<br>Prompt pay and<br>Other allowances | Rebates, Customer<br>Fees/Credits<br>and Co-Pay<br>Assistance | Totals          |
|---|---|---|-----------------|
|   | \$ 365  | \$ 430  | \$ 795          |
| <b>Balance at December 31, 2023</b>         |   |   |                 |
| Provision related to sales made in:         |   |   |                 |
| Current period                              | 352   | 1,640   | 1,992           |
| Prior periods                               | —   | —   | —               |
| <b>Payments and customer credits issued</b> | <b>( 497 )</b>  | <b>( 104 )</b>  | <b>( 601 )</b>  |
| <b>Balance at March 31, 2024</b>            | <b>\$ 220</b>   | <b>\$ 1,966</b>   | <b>\$ 2,186</b> |

The allowances for chargebacks, fees due to customers, rebates and discounts for prompt payment are recorded as a contra-asset to accounts receivable, while Medicaid rebates and return allowances are in accrued liabilities in the accompanying consolidated balance sheets.

#### **Trade Receivables**

The Company records gross trade receivables at the time of product sale to its customers. Amounts estimated for the associated chargebacks, cash discounts for prompt payment and any allowances for credit losses are booked as a reserve against accounts receivable and reduction of revenue. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company considers various factors, including loss history, individual credit risk associated with each customer, and the current and future condition of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such a customer. Customers in the United States are specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low. Sales abroad to non-specialty distributors have the potential for losses. It is the policy of the Company to use a sliding scale to establish a reserve of its gross sales to non-specialty distributors, based on aging category. The Company had a balance in allowance for credit losses of \$ 1,103 as of March 31, 2024.

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

Cost of products sold is related to the Company's product revenues for PEDMARK® and consists primarily of product production costs associated with finished goods inventory and royalty payments ( 1 % of net sales) the Company is required to pay to Oregon Health & Science University ("OHSU") on all net sales of PEDMARK®. Cost of products sold also consists of shipping and other third-party logistics and distribution costs for PEDMARK®. The Company considered regulatory approval of PEDMARK® to be uncertain and product manufactured prior to regulatory approval could not have been sold unless regulatory approval was obtained. As such, the manufacturing costs for PEDMARK® incurred prior to regulatory approval were not capitalized as inventory but were expensed as research and development costs. After FDA approval in September 2022, the Company had various lots of PEDMARK® in various stages of production in connection with the product launch in the fourth quarter of 2022. As of March 31, 2024, the Company capitalized approximately \$ 2,064 of costs as inventory on the condensed consolidated balance sheet. Of the items capitalized, \$ 774 was capitalized as work in process and raw materials, \$ 1,290 was capitalized into finished goods, \$ 550 of that being reclassified to cost of product sold.

### **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. As of March 31, 2024, the Company had \$ 51,184 in cash, savings and money market accounts (\$ 13,269 at December 31, 2023). As of March 31, 2024, the Company held \$ 1,314 in cash of which \$ 363 (as presented in U.S. dollars) was held in foreign currencies (\$ 570 at December 31, 2023 as presented in U.S. dollars). As of March 31, 2024, the Company held \$ 49,870 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 March 31, 2024 and December 31, 2023 consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and term loans, the carrying values of which approximate fair value due to their relatively short time to maturity or interest rates that approximate market interest rates. The Company does not hold or issue financial instruments for trading.

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

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

### **Common Shares and Warrants**

As of March 31, 2024, the Company has 0.2 million warrants with a weighted average strike price of \$ 7.71 outstanding to purchase common shares that have a weighted average life of 3.80 years.

### **Research and Development Costs and Investment Tax Credits**

Research costs, including employee compensation, laboratory fees, lab supplies, and research and testing performed under contract by third parties, are expensed as incurred. Development costs, including drug substance costs, clinical study expenses and regulatory expenses are expensed as incurred.

Investment tax credits, which are earned as a result of qualifying research and development expenditures, are recognized when the expenditures are made and their realization is reasonably assured. They are applied to reduce related capital costs and research and development expenses in the year recognized.

### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, and accounts receivable. The Company maintains deposits in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the high credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument.

The Company's trade receivables includes amounts billed to Customers for product sales of PEDMARK ®. In the U.S., the customers are a limited group of specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low. The Company also sells to a select group of global distributors. These global

distributors are established companies and although the Company regards credit losses with these distributors to be remote, it does recognize the potential for credit losses with this group.

#### **Income Taxes**

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of March 31, 2024, we maintained a full valuation allowance against our deferred tax assets.

The provisions of the Financial Accounting Standards Board ("FASB") ASC 740-10, *Uncertainty in Income Taxes*, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position.

#### **Foreign Currency Transactions**

The U.S. dollar is the functional currency for the Company's consolidated operations. All gains and losses from currency transactions are included in results of operations.

#### **Net Income/(Loss) Per Share**

Basic net income/(loss) per share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted net income/(loss) per share is computed using the same method, except the weighted average number of common shares outstanding includes convertible debentures, stock options and warrants, if dilutive, as determined using the if-converted method and treasury methods. Accordingly, warrants to purchase 116 of our common shares, restricted share units to purchase 214 of our common shares, convertible notes convertible into 2,968 of our common shares and options to purchase 1,702 of our common shares at March 31, 2024, were not included in earnings per share. Such warrants, options and convertible notes would have an antidilutive effect. In 2023, warrants to purchase 150 of our common shares, convertible notes convertible into 3,127 of our common shares and options to purchase 5,032 common shares were excluded from the computation of loss per share as their inclusion would have been antidilutive.

#### **Recent Accounting Pronouncements**

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

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

### 3. Income/(loss) per Share

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

|   | Three Months Ended March 31, |                    |
|---|------------------------------|--------------------|
|   | 2024                         | 2023               |
| <b>Numerator:</b>                                     |                              |                    |
| Net income/(loss)                                     | \$ 12,837                    | \$ ( 6,052 )       |
| <b>Denominator:</b>                                   |                              |                    |
| Weighted-average common shares, basic                 | 27,045                       | 26,559             |
| Dilutive effect of stock options                      | 3,005                        | —                  |
| Dilutive effect of restricted share units             | 214                          | —                  |
| Dilutive effect of warrants                           | 34                           | —                  |
| Dilutive effect of convertible debt                   | 793                          | —                  |
| Incremental dilutive shares                           | 4,046                        | —                  |
| Weighted-average common shares, diluted               | 31,091                       | 26,559             |
| <b>Net income/(loss) per share, basic and diluted</b> | <b>\$ 0.41</b>               | <b>\$ ( 0.23 )</b> |

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

|  | Three Months Ended March 31, |       |
|--|------------------------------|-------|
|  | 2024                         | 2023  |
| Options to purchase common shares                | 1,762                        | 5,032 |
| Convertible debt to purchase common shares       | 2,968                        | 3,127 |
| Restricted share units to purchase common shares | —                            | 298   |
| Warrants to purchase common shares               | 116                          | 150   |

### 4. Stockholders' Equity

#### Authorized Capital Stock

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

### **Warrants to Purchase Common Stock**

During the three months ended March 31, 2024, and 2023, there were no warrants issued or exercised. Outstanding warrants have a weighted average life of 3.80 years on March 31, 2024. The following tables detail the Company's warrant activity for the three months ended March 31, 2024, and 2023, respectively:

| Investor Warrants                 | Common Shares<br>Issuable Upon Exercise<br>of Outstanding<br>Warrants | Weighted-Average<br>Exercise Price |
|-----------------------------------|---|------------------------------------|
| Outstanding December 31, 2023     | 150   | \$ 7.71                            |
| Issued                            | —   | —                                  |
| <b>Outstanding March 31, 2024</b> | <b>150</b>  | <b>\$ 7.71</b>                     |

| Investor Warrants                 | Common Shares<br>Issuable Upon Exercise<br>of Outstanding<br>Warrants | Weighted-Average<br>Exercise Price |
|-----------------------------------|---|------------------------------------|
| Outstanding December 31, 2022     | 150   | \$ 7.71                            |
| Issued                            | —   | —                                  |
| <b>Outstanding March 31, 2023</b> | <b>150</b>  | <b>\$ 7.71</b>                     |

### **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 shares outstanding as of March 31, 2024, a maximum of 6,776 shares of common stock are authorized for issuance pursuant to stock options or other equity awards granted under the Plan. For all options issued under the Plan, the exercise price is the fair value of the underlying shares on the date of grant. All options vest within three years or less and are exercisable for a period of ten years from the date of grant. The Plan allows the issuance of Canadian and U.S. dollar grants. The table below outlines recognized employee expense from equity awards for the three-month period ended March 31, 2024, and 2023.

|  | Three Months Ended March 31, |                 |
|--|------------------------------|-----------------|
|  | 2024                         | 2023            |
| Employee options expense recognized    | \$ 1,191                     | \$ 1,089        |
| <b>Total option expense recognized</b> | <b>\$ 1,191</b>              | <b>\$ 1,089</b> |

### **Stock Option Activity**

The following is a summary of option activity for the three months ended March 31, 2024, and 2023.

|                                      | Number of<br>Options (thousands) | Weighted-Average<br>Exercise Price |
|--------------------------------------|----------------------------------|------------------------------------|
| Outstanding at December 31, 2023     | 4,798                            | \$ 6.27                            |
| Granted                              | 45                               | 7.29                               |
| Exercised                            | ( 75 )                           | 5.81                               |
| Forfeited                            | —                                | —                                  |
| <b>Outstanding at March 31, 2024</b> | <b>4,768</b>                     | <b>\$ 6.29</b>                     |

|                                      | Number of<br>Options (thousands) | Weighted-Average<br>Exercise Price |
|--------------------------------------|----------------------------------|------------------------------------|
| Outstanding at December 31, 2022     | 4,539                            | \$ 5.43                            |
| Granted                              | 580                              | 8.12                               |
| Exercised                            | ( 47 )                           | 4.36                               |
| Forfeited                            | ( 40 )                           | 6.98                               |
| <b>Outstanding at March 31, 2023</b> | <b>5,032</b>                     | <b>\$ 5.43</b>                     |

Of the 4,768 options granted and outstanding at March 31, 2024, 3,857 are fully vested and exercisable.

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

| Black-Scholes Model Assumptions | Valuation Assumptions<br>March 31, 2024 |
|---------------------------------|---|
| Expected dividend               | - %                                     |
| Risk free rate                  | 4.73 %                                  |
| Expected volatility             | 48 %                                    |
| Expected life                   | 1.50 years                              |

#### Restricted Share Units Activity

The Plan allows for the issuance of restricted share units ("RSUs"). The following is a summary of RSU activity for the three months ended March 31, 2024, and 2023. During the three months ended March 31, 2024, 17 RSUs were awarded, 21 were released from restriction and none were forfeited. For the same period in 2023, 264 RSUs were awarded, 1 was released from restriction and none were forfeited. The Company recognized \$ 0.3 million in RSU expense for the three months ended March 31, 2024, and \$ 0.03 million for the same period in 2023. Standard vesting of RSUs is over three years with 1/3 vesting on the first anniversary date of the grant and then 1/24 on the last day of each subsequent month. The Compensation Committee may also award RSUs with alternative vesting.

| RSUs Current Year                    | Number of Restricted<br>Share Units (thousands) |
|--------------------------------------|---|
| Outstanding at December 31, 2023     | 218   |
| Awarded                              | 17  |
| Released                             | ( 21 )  |
| <b>Outstanding at March 31, 2024</b> | <b>214</b>                                      |

| RSUs Past Year                       | Number of Restricted<br>Share Units (thousands) |
|--------------------------------------|---|
| Outstanding at December 31, 2022     | 35  |
| Awarded                              | 264   |
| Released                             | ( 1 )   |
| <b>Outstanding at March 31, 2023</b> | <b>298</b>                                      |

The value of RSUs issued was estimated using the share price on the date of the award multiplied by the number of shares granted.

## 5. Fair Value Measurements

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

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Financial assets and liabilities are classified in their entirety within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The Company measures the fair value of the Processa Pharmaceuticals, Inc ("Processa") common shares held by the Company by taking into consideration valuations obtained from public financial markets. The Company uses Yahoo Finance to obtain share price data and Oanda for foreign currency pricing services to estimate fair value. These inputs include reported trades of and broker-dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

As of March 31, 2024, the Company had financial assets valued based on Level 1 inputs consisting of cash and cash equivalents and had financial assets based on Level 2 inputs consisting of Processa common shares. During the three months ended March 31, 2024, the Company did not have any transfers of financial assets between Levels 1 and 2.

| Fair Value Measurement at March 31, 2024 and December 31, 2023<br>(in thousands) |   |      |                                     |      |                                 |           |      |      |                   |  |
|--|---|------|-------------------------------------|------|---------------------------------|-----------|------|------|-------------------|--|
|  | Quoted Price in Active Market for Identical Instruments |      | Significant Other Observable Inputs |      | Significant Unobservable Inputs |           |      |      | Total             |  |
|  | Level 1   |      | Level 2                             |      | Level 3                         |           |      |      |                   |  |
|  | 2024  | 2023 | 2024                                | 2023 | 2024                            | 2023      | 2024 | 2023 |                   |  |
| <b>Assets</b>  |   |      |                                     |      |                                 |           |      |      |                   |  |
| Cash and cash equivalents  | \$ 1,314  | (1)  | \$ 1,340                            | (1)  | \$ 49,870                       | \$ 11,929 | \$ - | \$ - | \$51,184 \$13,269 |  |
| Processa common shares   | \$ 4  | (2)  | \$ 25                               | (2)  | \$ -                            | \$ -      | \$ - | \$ - | \$4 \$25          |  |

(1) The Company held approximately \$ 1,314 in cash as of March 31, 2024, of which approximately \$ 363 was held in foreign currencies (translated into U.S. dollars). As of December 31, 2023, the Company held approximately \$ 1,340 in cash of which approximately \$ 570 was in foreign currencies (translated into U.S. dollars).

(2) The Company holds 4 1 unrestricted common shares of Processa (NASDAQ:PCSA).

## 6. Commitments and Contingencies

### Oregon Health & Science University Agreement

On February 20, 2013, Fennec entered into a new exclusive license agreement with OHSU for exclusive worldwide license rights to intellectual property directed to thiol-based compounds, including PEDMARK® and their use in oncology (the "OHSU Agreement"). OHSU will receive certain milestone payments, royalty on net sales for licensed products and 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 PEDMARK® for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments entered in the OHSU Agreement including but not limited to the royalty rate on net sales for licensed products, royalty rate from sublicensing of the licensed technology and the fee payable upon the regulatory approval of a

licensed product. Certain milestone payments are due upon FDA approval and achievement of sufficient positive EBITDA over a specified period. PEDMARK® received FDA approval in September 2022, however at this time, due to significant uncertainty surrounding timing and magnitude of certain milestones, the Company has only recorded a royalty liability associated with net revenue.

The term of the OHSU Agreement as amended by Amendment 1 expires on the date of the last to expire claim(s) covered in the patents licensed to Fennec or 8 years, whichever is later. The Company now has a licensed product with regulatory approval that is covered by the Orphan Drug Designation, the parties amended the term of the agreement. Sodium thiosulfate is currently protected by methods of use patents that the Company exclusively licensed from OHSU that expired in Europe in 2021 and that expire in the United States in 2038. The OHSU Agreement is terminable by either Fennec or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. Fennec also has the right to terminate the OHSU Agreement at any time upon 60 days prior written notice and payment of all fees due to OHSU under the OHSU Agreement. The Company had accrued approximately \$ 77 ( 1 % net sales) in royalty expense to OHSU for the period ended March 31, 2024. Total amount accrued in royalty expense to OHSU as of March 31, 2024 was \$ 314 .

### **Litigation**

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

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00123) with the Patent Trial and Appeal Board ("PTAB") of the USPTO to invalidate U.S. Patent No. 10,596,190 (the "190 Patent"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using PEDMARK®. The '190 Patent was issued on March 24, 2020. On April 18, 2023, the PTAB invalidated the only claim of the '190 Patent. The final written decision became effective June 20, 2023. The '190 Patent was previously listed in the United States Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"). In light of PTAB's final written decision on the invalidity of the '190 Patent, we requested that the FDA remove the '190 Patent from the Orange Book. Two United States patent applications claiming priority through the '190 Patent remain pending at the United States Patent and Trademark Office ("USPTO").

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00125) to invalidate our wholly owned U.S. Patent No. 10,792,363 (the "363 Patent"), which relates to an anhydrous form of STS and its method of manufacture, which is the active pharmaceutical ingredient in the PEDMARK® product. The '363 Patent was issued October 6, 2020. During the '363 IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. Because the remaining claims in the '363 patent are directed to a method of manufacture, the '363 patent is not eligible for listing in the Orange Book. In September 2023, the PTAB issued a Final Written Decision in favor of Fennec and upholding the amended claim.

The USPTO has now granted four additional U.S. patents that cover the PEDMARK® formulation and its use, each of which have been, or are in the process of being, listed in the U.S. FDA's "Orange Book" (U.S. Patent No. 11,291,728 (issued April 5, 2022), U.S. Patent No. 11,510,984 (issued November 29, 2022), U.S. Patent No. 11,617,793 (issued April 4, 2023), and U.S. Patent No. 11,964,018 (issued April 23, 2024)). The USPO has also recently allowed two additional patent applications (U.S. Patent Application Nos. 17/992,703 and 17/992,707) that cover the use of the PEDMARK® formulation. Five additional United States patent applications from this family are pending at the USPTO covering various sodium thiosulfate formulations and uses. We plan to vigorously defend our intellectual property rights to PEDMARK® if challenged. An invalidation of our patents covering PEDMARK® could have a material adverse effect on our ability to protect our rights in PEDMARK® beyond periods of marketing exclusivity for PEDMARK® in the United States under Orphan Drug Designation.

#### *CIPLA Litigation*

On December 1, 2022, we received a letter dated November 30, 2022, notifying us that CIPLA Ltd. and CIPLA USA ("CIPLA") submitted to the FDA an ANDA (ANDA No. 218028) for a generic version of PEDMARK® (sodium thiosulfate solution) that contains Paragraph IV Certifications on two of our patents covering PEDMARK®: the OHSU

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licensed '190 Patent, expiration date January 2038; and our US 11,291,728 Patent (the "728 Patent"), expiration date July 2039. On January 6, 2023, we received a letter dated January 5, 2023, notifying us that CIPLA submitted to the FDA a Paragraph IV Certification on our newly issued US 11,510,984 Patent (the "984 Patent"). These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for PEDMARK®. The certifications allege these patents are invalid or will not be infringed by the manufacture, use, or sale of CIPLA's sodium thiosulfate solution.

Under the Food and Drug Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, after receipt of a valid Paragraph IV notice, the Company may bring a patent infringement suit in a federal district court against CIPLA within 45 days from the receipt of the Notice Letter and if such a suit is commenced within the 45 -day period, the Company is entitled to a 30 month stay on the FDA's ability to give final approval to any proposed products that reference PEDMARK®. In addition to the 30 -month stay, because we have received Orphan Drug Exclusivity, the FDA may not approve CIPLA's ANDA for at least 7 years from PEDMARK®'s FDA approval date of September 20, 2022.

On January 10, 2023, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:23-cv-00123), for infringement of the '190 Patent, the '728 Patent, and the '984 Patent. On April 20, 2023, we filed an Amended Complaint to assert infringement of the '728 patent and the '984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the "793 Patent") covering the formulation of the PEDMARK® product, which was listed in the Orange Book on or around April 17, 2023, and has an expiration date of July 2039. On May 11, 2023, we received written notice of CIPLA's Paragraph IV Certification as to the '793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the '793 Patent is invalid, unenforceable, and/or will not be infringed by CIPLA's ANDA Product. On July 27, 2023, we filed a Second Amended Complaint to assert the '793 Patent. CIPLA filed an Answer to the Second Amended Complaint on August 31, 2023. The suit is ongoing.

PEDMARQSI® (EU Brand name for PEDMARK®) received European Commission approval in June 2023 and was granted 10 years of market exclusivity in Europe under Pediatric Use ("PUMA").

### **Executive Severance**

In the event of termination of Mr. Raykov's (Chief Executive Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one -time severance payment equal to twelve months of salary (currently \$ 608 ). In the event of termination of Mr. Andrade's (Chief Financial Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one -time severance payment equal to six months of salary (currently \$ 220 ). In the event of termination of Mr. Haigh's (Chief Operating Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one -time severance payment equal to three months of salary (currently \$112 as translated to US dollars at March 31, 2024).

### **Leases**

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

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

On August 1, 2023, the Company entered into a second Office Service Agreement (the "Second Office Service Agreement") with Regus to lease office space in Dublin, Ireland. Per the terms of the Second Office Service Agreement, the monthly rent payments are \$ 2 . The Company was required to pay a security deposit of \$ 5 , which is the equivalent of two months' rent. The Second Office Service Agreement commenced on August 1, 2023 and terminates on January 31,

2025, thereafter the lease may continue on a month-to-month basis with either party being able to terminate the agreement by providing one months' advance written notice of termination.

The Second Office Service Agreement does not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring the operating lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate consisting of the current prime rate plus 150 basis points for operating leases that commenced after August 2023. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

| <b>March 31, 2024</b>   |           |           |
|---|-----------|-----------|
| Remaining lease terms (in months)   |           | 10        |
| Discount rate   |           | 10 %      |
| Maturities of lease liabilities as of December 31, 2023 were as follows (in thousands): |           |           |
| Year Ending December 31,  |           |           |
| 2024  | \$        | 15        |
| 2025  |           | 2         |
|   |           | <u>17</u> |
| Less imputed interest   |           | 2         |
| Total lease liabilities   | <u>\$</u> | <u>15</u> |
| Current operating lease liabilities   | \$        | 17        |
| Non-current operating lease liabilities   |           | -         |
| Total lease liabilities   | <u>\$</u> | <u>17</u> |

#### **Employee Benefit Plan**

In May 2021, the Company established the Fennec Pharmaceuticals, Inc. 401(k) Plan (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code of 1986. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. As of March 31, 2024, the Company does not offer matching contributions.

#### **7. Term Loans**

On August 1, 2022, the Company entered into the SPA with the Investor in connection with the issuance of up to \$ 45,000 of Notes, issuable in multiple tranches (see Note 1). On August 19, 2022, the Company closed on the initial tranche of \$ 5,000 , which has an Initial Conversion Price equal to \$ 8.11 per share, which was calculated based on a 20 % premium of the 5 -day VWAP immediately prior to the announcement of the SPA. In connection with the first closing, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of \$ 5,000 . The Notes become due on the maturity date, which is August 19, 2027.

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

Subsequent to the funding of the Second Closing Note, and before December 31, 2023, the Company may draw up to \$ 20,000 of additional financing under the SPA, in one or more tranches of \$ 10,000 upon mutual agreement of the Company

and the Investor (the "Subsequent Closing Notes"). The Subsequent Closing Notes will be convertible at a price per share equal to \$ 7.89 per share, which price is calculated on the same basis as for the Second Closing Note.

A commitment fee of 2.0 % of the Notes was payable under the SPA, which was paid by the Company issuing the Investor warrants to purchase 110,996 of the Company's common shares (one half issued at the first closing and the other half issued at the second closing). The warrants are exercisable at a price per share of \$ 8.11 and have a term of five years from the date of the grant.

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

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

Cash interest on outstanding principal shall accrue at a rate of prime, plus 4.5 % per annum, from the date of funding ( 11 % as of March 31, 2024). Cash interest is due on the first business day of each calendar quarter ("Interest Date"). Payment-in-kind ("PIK") interest will commence on funding date and accrue at a rate of 3.5 % per annum. PIK interest will stop accruing on August 24, 2024. Any accrued PIK interest shall remain outstanding and be payable on each Interest Date and be added to the outstanding principal amount. The Company has accrued \$ 1.6 million in PIK interest and has classified the PIK interest in long-term liabilities.

The Notes are convertible into fully paid, non-assessable shares of the Company's common shares at any point after their issuance dates and before the maturity date. Any amount of the Notes may be converted into common shares so long as it does not create partial shares. The conversion rate is determined by dividing the conversion amount by the conversion price. Provisions of the SPA create legal, valid and enforceable liens on, and security interests in, all of the Company's and each of its subsidiaries assets.

Aggregate annual payments under the SPA as of December 31, 2023, are as follows (in thousands):

| <b>Years Ending December 31,</b>      | <b>Amount</b> |
|---------------------------------------|---------------|
| 2024                                  | —             |
| 2025                                  | —             |
| 2026                                  | —             |
| 2027                                  | 30,000        |
| Payment in kind interest              | 1,617         |
| Total future payments                 | 31,617        |
| Less: unamortized debt discount       | ( 268 )       |
| Total term loan, net of debt discount | \$ 31,349     |

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

Debt issuance costs of \$ 175 were paid in cash for legal fees and to the Investor in 2022 and warrants valued at \$ 441 were granted the Investor to secure access to the SPA. These amounts were capitalized and are being amortized over the access period of the SPA. Upon drawing tranche 1 and tranche 2, the Company recorded a debt discount of \$ 314 , which was based on a pro-rata allocation of the issue costs to secure the SPA, reducing the capitalized amount by the same amount. The debt discount is being amortized over the life of the SPA.

## **8. License Agreement**

### *License Agreement with Norgine Pharma UK Limited*

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

Pursuant to the terms of the Agreement, Fennec shall receive the following payments from Norgine: (i) an upfront payment in the amount of € 40 million or approximately \$ 43.2 million, which was paid to Fennec on March 15, 2024, (ii) up to € 210 million (or approximately \$ 230 million) upon the achievement of certain regulatory and commercial milestones, and (iii) tiered royalty payments based on net sales of PEDMARQSI® in the Territory, which royalty payment range from mid-teen percent to mid-twenty percent based on the aggregate net sales of PEDMARQSI® in the Territory. The tiered royalty payments are subject to material reduction if an alternative or generic version of PEDMARQSI® becomes available in any respective country or jurisdiction within the Territory.

Subject to customary rights of each party to earlier terminate the Agreement, the term of the Agreement continues for the longer of: (i) March 15, 2034, or (ii) with respect to any particular country in the Territory, (a) the expiration of regulatory market exclusivity for PEDMARQSI® in such country, or (b) the last-to-expire of all patents for PEDMARQSI® in such country. The term of the Agreement shall be automatically renewed for additional three-year periods unless either party provides the other party written notice of its intent not to renew the Agreement at least one year prior to the applicable termination date of the Agreement.

The Company evaluated the Norgine License Agreement under ASC 606 and concluded that Norgine represents a customer in the transaction. There were two performance obligations: A license of functional IP and a material right for future supply. The Company will allocate the transaction price, including currently unrecognized variable consideration, to the two performance obligations based on estimated standalone selling price, which was estimated using projected cash flows. The initial transaction price consisted of the non-refundable upfront payment, a portion of which was allocated to and recognized as License Revenue in the first quarter of 2024 as the requirements for revenue recognition under ASC 606 were met. The portion of the transaction price associated with the material right is deferred and reflected as deferred revenue in the condensed consolidated balance sheets. Deferred revenue associated with the material right is recognized as contract liabilities under the supply arrangement are made. The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are dependent on regulatory approvals and actions of third parties, and thus are highly susceptible to factors outside the Company's influence. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue or deferred as part of the material right in the period when the related sales threshold is met. All other milestones will be recognized as revenue or deferred as part of the material right immediately in the period the underlying milestone is achieved. Any consideration related to sales-based royalties will be recognized as revenue or deferred as part of the material right when the related sales occur. For the three months ended March 31, 2024, the Company did not recognize any milestone or royalty revenue payments from the Norgine sales of PEDMARQSI® Agreement.

In conjunction with entering into the Agreement, the Company paid approximately \$ 1.7 million in incremental costs, which were capitalized and recorded within Other non-current assets. The Company amortizes the asset over the period of expected benefit using a systematic basis that reflects the pattern of transfer to the customer. A portion that represents the license was recognized immediately and is recorded within selling and marketing expense in the consolidated statements of operations. As of March 31, 2024, \$ 1.0 million in incremental cost was capitalized.

## **9. Subsequent Events**

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

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

#### **Caution Concerning Forward-Looking Statements**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 29, 2024 (the "Annual Report") and our unaudited interim condensed consolidated financial statements and related notes appearing in this Quarterly Report on Form 10-Q (the "Quarterly Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to the Company's plans and strategy for its business, includes forward looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements can be identified by words such as "future," "anticipates," "believes," "estimates," "expects," "intends," "plans," "predicts," "will," "would," "could," "can," "may," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. As a result of many factors, including those factors set forth in Part I, Item 1A of the Annual Report under the heading "Risk Factors", our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2023, and the condensed consolidated financial statements and accompanying notes included elsewhere in this report.

#### **Overview**

We are a commercial-stage biopharmaceutical company focused on our only product candidate PEDMARK®. On September 20, 2022, we received approval from the U.S. Food and Drug Administration ("FDA") for PEDMARK® (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. This approval makes PEDMARK® the first and only treatment approved by the FDA in this area of significant unmet medical need. On October 17, 2022, we announced commercial availability of PEDMARK® in the United States. Further, PEDMARQSI® (PEDMARK® brand name outside of U.S.) received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

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

Under the terms of the licensing agreement, we received approximately \$43.2 million in upfront consideration and may receive up to approximately \$230 million in additional commercial and regulatory milestone payments and double-digit tiered royalties on net sales of PEDMARQSI® in the licensed territories up to the mid-twenties. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

We sell PEDMARK® in the United States through an experienced field force including Regional Pediatric Oncology Specialists and medical science liaisons who are helping to educate the medical communities and patients about cisplatin induced ototoxicity and our programs supporting patient access to PEDMARK®. Sales outside of the U.S. are through experienced distributors which market and promote PEDMARK® in developing markets.

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

We received Orphan Drug Exclusivity for PEDMARK® in January 2023, which provides seven years of market exclusivity in the United States from its FDA approval on September 20, 2022, until September 20, 2029. The USPTO has now granted four additional U.S. patents that cover the PEDMARK® formulation and its use, each of which have been, or are in the process of being, listed in the U.S. FDA's "Orange Book" (U.S. Patent No. 11,291,728 (issued April 5, 2022), U.S. Patent No. 11,510,984 (issued November 29, 2022), U.S. Patent No. 11,617,793 (issued April 4, 2023), and U.S. Patent No. 11,964,018 (issued April 23, 2024)). The USPO has also recently allowed two additional patent applications (U.S. Patent Application Nos. 17/992,703 and 17/992,707) that cover the use of the PEDMARK® formulation. Five additional United States patent applications from this family are pending at the USPTO covering various sodium thiosulfate formulations and uses. We are also pursuing additional patent applications in both the U.S. and internationally for PEDMARK®.

There can be no assurance that we do not or will not infringe on patents held by third parties or that third parties in the future will not claim that we have infringed on their patents. In the event that our product or technologies infringe or violate the patent or other proprietary rights of third parties, there is a possibility we may be prevented from pursuing product development, manufacturing or commercialization of our product until the underlying patent dispute is resolved. For example, there may be patents or patent applications held by others that contain claims that our product or operations might be determined to infringe or that may be broader than we believe them to be. Given the complexities and uncertainties of patent laws, there can be no assurance as to the impact that future patent claims against us may have on our business, financial condition, results of operations, or prospects.

#### **PEDMARK® Product Overview**

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

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

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

#### **Cisplatin Induced Ototoxicity**

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

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The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids or cochlear implants, which can be helpful for some, but do not reverse the hearing loss and can be costly over time. Infants and young children that are affected by ototoxicity at critical stages of development lack speech and language development and literacy, and older children and adolescents often lack social-emotional development and educational achievement.

Although we have obtained applicable regulatory approval to sell PEDMARK® in the United States and approval for PEDMARQSI in Europe and U.K., we recognize there may still be a need to establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue.

We generated net income of approximately \$12.8 million for the three months ended March 31, 2024, and a net loss of \$6.1 million for the same period in 2023. As of March 31, 2024, our accumulated deficit was approximately \$206.4 million (\$219.2 million at December 31, 2023).

We believe that our cash and cash equivalents as of March 31, 2024, which totaled \$51.2 million and cash from product sales, will be sufficient to meet our cash requirements through at least the next twelve months. We anticipate the Norgine licensing deal will alleviate the need to find alternative sources of financing and help us to fund operations while we expand our markets to areas outside of U.S., Europe, Australia and New Zealand. We continue to look to establish collaborations that will provide us with funding for the out-license or sale of certain aspects of our intellectual property portfolio or from other sources.

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

## Results of Operations

Three months ended March 31, 2024 versus three months ended March 31, 2023:

| In thousands of U.S. Dollars             | Three Months Ended<br>March 31, 2024 | %            | Three Months Ended<br>March 31, 2023 | %            | Change           |
|--|--------------------------------------|--------------|--------------------------------------|--------------|------------------|
| PEDMARK product sales, net               | \$ 7,419                             |              | \$ 1,677                             |              | \$ 5,742         |
| Licensing revenue                        | 17,958                               |              | —                                    |              | 17,958           |
| <b>Total revenue</b>                     | <b>25,377</b>                        |              | <b>1,677</b>                         |              | <b>23,700</b>    |
| <b>Operating expenses:</b>               |                                      |              |                                      |              |                  |
| Cost of product sales                    | 550                                  | 5            | 95                                   | 1            | 455              |
| Research and development                 | 3                                    | 0 %          | 4                                    | 0 %          | (1)              |
| Selling and marketing                    | 5,209                                | 45 %         | 2,531                                | 36 %         | 2,678            |
| General and administration               | 5,872                                | 50 %         | 4,317                                | 62 %         | 1,555            |
| <b>Total operating expense</b>           | <b>11,634</b>                        | <b>100 %</b> | <b>6,947</b>                         | <b>100 %</b> | <b>4,687</b>     |
| Income/(loss) from operations            | 13,743                               |              | (5,270)                              |              | 19,013           |
| Unrealized loss on securities            | (11)                                 |              | (30)                                 |              | 19               |
| Amortization expense                     | (20)                                 |              | (72)                                 |              | 52               |
| Interest expense                         | (1,034)                              |              | (798)                                |              | (236)            |
| Unrealized foreign exchange loss         | (38)                                 |              | 9                                    |              | (47)             |
| Interest income                          | 197                                  |              | 109                                  |              | 88               |
| <b>Net income/(loss) from operations</b> | <b>\$ 12,837</b>                     |              | <b>\$ (6,052)</b>                    |              | <b>\$ 18,889</b> |

- The Company recorded net product sales of \$7.4 million and \$18.0 million in licensing revenue related to the Norgine transaction for the three-month period ended March 31, 2024, compared to \$1.7 million in product sales and no licensing revenue for the same period in 2023. The Company recorded discounts and allowances against sales in the amount of \$2.1 million and cost of products sold of \$0.6 million for the three-month period ended March 31, 2024. For the same period in 2023, the Company recorded \$0.2 million in discounts and allowances and \$0.1 million in cost of goods sold.
- Selling and marketing expenses include distribution costs, logistics, shipping and insurance, advertising, wages commissions and out-of-pocket expenses. The Company recorded \$5.2 million in selling and marketing expenses for the period ended March 31, 2024, compared to \$2.5 million for the same period in 2023. The increase is largely related to increased payroll and additional marketing expenses in the comparable period.
- There was a \$1.6 million increase in general and administrative expenses for the three-months ended March 31, 2024, compared to same period in 2023. There was an increase in consulting and professional costs of approximately \$1.7 million for the three-months ended March 31, 2024, compared to same period in 2023 which is largely attributable to increased European pre-commercialization related expenses.
- The value of the Processa Pharmaceuticals, Inc. ("Processa") shares held by us declined by \$0.01 million for three-months ended March 31, 2024. The shares declined in value by \$0.03 during same period in 2023. We acquired the Processa shares on October 30, 2020. The Processa shares are marked to market at each balance sheet date with the resulting change in value being booked as an unrealized gain or loss.
- Amortization expense decreased by \$0.1 million for three-months ended March 31, 2024, over same period in 2023.
- Interest expenses increased by \$0.2 million for the three-month ended March 31, 2024 compared to same period in 2023. The increase was driven mainly by higher average debt balances and higher interest rates on long-term debt.
- Interest income increased by \$0.1 million for the three-months ended March 31, 2024, as compared to same period in 2023, due to higher rates on money market accounts for the comparable periods.

### Quarterly Information

The following table presents selected condensed financial data for each of the last eight quarters through March 31, 2024, as prepared under generally accepted accounting principles within the United States, or U.S. GAAP (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 |
|--------------------|----------------------------------|--|--|
| June 30, 2022      | \$ (5,075)                       | \$ (0.19)                                | \$ (0.19)                                  |
| September 30, 2022 | (8,089)                          | (0.31)                                   | (0.31)                                     |
| December 31, 2022  | (6,857)                          | (0.26)                                   | (0.26)                                     |
| March 31, 2023     | (6,052)                          | (0.23)                                   | (0.23)                                     |
| June 30, 2023      | (5,444)                          | (0.21)                                   | (0.21)                                     |
| September 30, 2023 | (1,867)                          | (0.07)                                   | (0.07)                                     |
| December 31, 2023  | (2,682)                          | (0.10)                                   | (0.10)                                     |
| March 31, 2024     | 12,837                           | 0.47                                     | 0.41                                       |

### Liquidity and Capital Resources

| Selected Asset and Liability Data (thousands):        | As at<br>March 31, 2024 | As at<br>December 31, 2023 |
|---|-------------------------|----------------------------|
| Cash and equivalents                                  | \$ 51,184               | \$ 13,269                  |
| Other current assets                                  | 16,987                  | 13,589                     |
| Current liabilities                                   | 9,836                   | 7,553                      |
| Working capital <sup>(1)</sup>                        | 58,335                  | 19,305                     |
| <sup>(1)</sup> [Current assets – current liabilities] |                         |                            |

  

| Selected Equity:                            |           |           |
|---|-----------|-----------|
| Common stock and additional paid in capital | 208,179   | 206,380   |
| Accumulated deficit                         | (206,408) | (219,245) |
| Stockholders' equity/(deficit)              | 3,014     | (11,622)  |

Cash and cash equivalents were \$51,184 as of March 31, 2024, and \$13,269 at December 31, 2023. The increase in cash and cash equivalents between March 31, 2024, and December 31, 2023, is the result of cash outlays for operating expenses related to the promotion of our product, small amounts of research and development and general and administrative expenses, which were offset by cash inflows of \$43,204 from Norgine licensing deal, cash collections on product sales of \$3,115 and cash inflows of \$627 from various option exercises. There was an increase of \$3,398 in other current assets between March 31, 2024, and December 31, 2023, and an increase in current liabilities of \$2,283. The overall result was an increase in working capital of \$39,030.

The following table illustrates a summary of cash flows data for the three-month periods of March 31, 2024 and 2023:

| Selected Cash Flow Data<br>(dollars and shares in thousands) | Three Months Ended<br>March 31, 2024 |  | Three Months Ended<br>March 31, 2023 |  |
|--|--------------------------------------|--|--------------------------------------|--|
|  |                                      |  |                                      |  |
| Net cash provided by operating activities                    | \$ 39,047                            |  | \$ (5,577)                           |  |
| Net cash provided by investing activities                    | —                                    |  | —                                    |  |
| Net cash provided by financing activities                    | (1,132)                              |  | 193                                  |  |
| Net cash flow  | \$ 37,915                            |  | \$ (5,384)                           |  |

Net cash used in operating activities for the three months ended March 31, 2024, primarily reflected a net income of \$12,837. The three-month income was adjusted for the add back of non-cash items consisting of \$1,191 in stock-based compensation expense, with unrealized loss on securities of \$11, PIK interest of \$398 and amortization expense of \$743 for the three months ended March 31, 2024. For the three months ended March 31, 2024, there was a net increase in accounts receivable, inventory, prepaid and other assets of \$3,414; coupled with a net increase in current liabilities of \$27,281. Approximately, \$25,246 of this increase relates to deferred revenue associated with the Norgine transaction.

Three-month positive cash flows from operating activities were \$39,047 and negative 5,577, respectively, for the periods ended March 31, 2024, and 2023. Net cash used in financing activities for the three months ended March 31, 2024, was \$1,132. During the same period in 2023, there were various equity exercises resulting in cash inflows from financing activities of \$193. Net cash flows from the three month-periods ended March 31, 2024 and 2023, were positive \$37,915 and negative \$5,384, 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 March 31, 2024 and December 31, 2023 was as follows (in thousands):

| <b>Outstanding Share Type</b> | <b>March 31, 2024</b> | <b>December 31, 2023</b> | <b>Change</b> |
|-------------------------------|-----------------------|--------------------------|---------------|
| Common shares                 | 27,105                | 26,411                   | 694           |
| Warrants                      | 150                   | 150                      | —             |
| Stock options                 | 4,767                 | 5,032                    | (265)         |
| <b>Total</b>                  | <b>32,022</b>         | <b>31,593</b>            | <b>429</b>    |

#### **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. As of March 31, 2024, we had approximately \$1.3 million in our cash accounts and \$49.9 million 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. Until we are cash flow positive from operations, we have chosen to avoid investments of a trading or speculative nature.

We classify fixed income investments with original maturities at the date of purchase greater than three months which mature at or less than twelve months as current. We carry investments at their fair value with unrealized gains and losses included in other comprehensive income (loss); however, we have not held any instruments that were classified as short-term investments during the periods presented in this Quarterly Report.

### **Off-Balance Sheet Arrangements**

Since our inception, we have not had any material off-balance sheet arrangements.

### **Contractual Obligations and Commitments**

None, other than the OHSU Agreement, lease agreements, and severance amounts described in notes to our condensed consolidated financial statements contained elsewhere in this Quarterly Report.

### **Critical Accounting Policies and Estimates**

A summary of our critical accounting policies and use of estimates are presented in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operation" of our Annual Report. There have been no material changes to our critical accounting policies and use of estimates during the three months ended March 31, 2024.

### **Revenue Recognition**

Under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company determines it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation(s). As part of the accounting for these arrangements, the Company must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

### **Stock-based Compensation**

The calculation of the fair values of our stock-based compensation plans requires estimates that require management's judgments. Under ASC 718, the fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model. The valuation models require assumptions and estimates to determine expected volatility, expected life, expected dividends and expected risk-free interest rates. The expected volatility was determined using historical volatility of our stock based on the contractual life of the award. The risk-free interest rate assumption was based on the yield on zero-coupon U.S. Treasury strips at the award grant date. We also used historical data to estimate forfeiture experience. In valuing options granted in the fiscal years ended March 31, 2024, we used the following weighted average assumptions:

| <b>Black-Scholes Model Assumptions</b> | <b>Valuation Assumptions<br/>March 31, 2024</b> |
|--|---|
| Expected dividend                      | - %   |
| Risk free rate                         | 4.73 %  |
| Expected volatility                    | 48 %  |
| Expected life                          | 1.50 years                                      |

### **Common shares and warrants**

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

### **Newly Adopted and Recent Accounting Pronouncements**

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

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

### **Item 3. Controls and Procedures.**

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

The Company's management, with the participation of our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of December 31, 2023. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports the Company files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, the Company's management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints that require the Company's management to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2023, the Company's disclosure controls and procedures were not effective because of a material weakness in the Company's internal control over financial reporting related to fees and allowances paid to distributors for distinct services.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's management evaluated the effectiveness of its internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that evaluation, the Company's management has concluded that, as of December 31, 2023, our internal controls over financial reporting were not effective because of the existence of a material weakness in internal control over financial reporting related to fees and allowances paid to distributors for distinct services.

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

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

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

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

- Enhance the formality of its review procedures with respect to accounting for new contracts with customers.
- Strengthen the review process to improve the operation of accounting and review controls with respect to complex and non-recurring transactions, as well as those transactions that require significant estimates and judgments.
- Engaging additional service providers or hiring additional full-time employees may be necessary and advisable to address these weaknesses.

The actions that the Company is taking are subject to ongoing senior management review as well as Audit Committee oversight. The Company is committed to maintaining a strong internal control environment and believes that these remediation efforts will represent significant improvements in its controls. The Company has started to implement these steps; however, some of these steps will take time to be fully integrated and confirmed to be effective and sustainable. Additional controls may also be required over time. Until the remediation steps set forth above are fully implemented and tested, the material weakness described above will continue to exist.

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

The Company is in the process of implementing changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) but does not believe any of these changes, as of the period covered by this Quarterly Report on Form 10-Q has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

**PART II: OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00123) with the Patent Trial and Appeal Board ("PTAB") of the USPTO to invalidate U.S. Patent No. 10,596,190 (the "190 Patent"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using PEDMARK®. The '190 Patent was issued on March 24, 2020. On April 18, 2023, the PTAB invalidated the only claim of the '190 Patent. The final written decision became effective June 20, 2023. The '190 Patent was previously listed in the United States Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"). In light of PTAB's final written decision on the invalidity of the '190 Patent, we requested that the FDA remove the '190 Patent from the Orange Book. Two United States patent applications claiming priority through the '190 Patent remain pending at the United States Patent and Trademark Office ("USPTO").

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed a Petition for inter partes review (IPR2022-00125) to invalidate our wholly owned U.S. Patent No. 10,792,363 (the "363 Patent"), which relates to an anhydrous form of

STS and its method of manufacture, which is the active pharmaceutical ingredient in the PEDMARK® product. The '363 Patent was issued October 6, 2020. During the '363 IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. Because the remaining claims in the '363 patent are directed to a method of manufacture, the '363 patent is not eligible for listing in the Orange Book. In September 2023, the PTAB issued a Final Written Decision in favor of Fennec and upholding the amended claim.

The USPTO has now granted four additional U.S. patents that cover the PEDMARK® formulation and its use, each of which have been, or are in the process of being, listed in the U.S. FDA's "Orange Book" (U.S. Patent No. 11,291,728 (issued April 5, 2022), U.S. Patent No. 11,510,984 (issued November 29, 2022), U.S. Patent No. 11,617,793 (issued April 4, 2023), and U.S. Patent No. 11,964,018 (issued April 23, 2024)). The USPO has also recently allowed two additional patent applications (U.S. Patent Application Nos. 17/992,703 and 17/992,707) that cover the use of the PEDMARK® formulation. Five additional United States patent applications from this family are pending at the USPTO covering various sodium thiosulfate formulations and uses. We plan to vigorously defend our intellectual property rights to PEDMARK® if challenged. An invalidation of our patents covering PEDMARK® could have a material adverse effect on our ability to protect our rights in PEDMARK® beyond periods of marketing exclusivity for PEDMARK® in the United States under Orphan Drug Designation.

*CIPLA Litigation*

On December 1, 2022, we received a letter dated November 30, 2022, notifying us that CIPLA Ltd. and CIPLA USA ("CIPLA") submitted to the FDA an ANDA (ANDA No. 218028) for a generic version of PEDMARK® (sodium thiosulfate solution) that contains Paragraph IV Certifications on two of our patents covering PEDMARK®: the OHSU licensed '190 Patent, expiration date January 2038; and our US 11,291,728 Patent (the "728 Patent"), expiration date July 2039. On January 6, 2023, we received a letter dated January 5, 2023, notifying us that CIPLA submitted to the FDA a Paragraph IV Certification on our newly issued US 11,510,984 Patent (the "984 Patent"). These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for PEDMARK®. The certifications allege these patents are invalid or will not be infringed by the manufacture, use, or sale of CIPLA's sodium thiosulfate solution.

Under the Food and Drug Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, after receipt of a valid Paragraph IV notice, the Company may bring a patent infringement suit in a federal district court against CIPLA within 45 days from the receipt of the Notice Letter and if such a suit is commenced within the 45-day period, the Company is entitled to a 30 month stay on the FDA's ability to give final approval to any proposed products that reference PEDMARK®. In addition to the 30-month stay, because we have received Orphan Drug Exclusivity, the FDA may not approve CIPLA's ANDA for at least 7 years from PEDMARK®'s FDA approval date of September 20, 2022.

On January 10, 2023, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:23-cv-00123), for infringement of the '190 Patent, the '728 Patent, and the '984 Patent. On April 20, 2023, we filed an Amended Complaint to assert infringement of the '728 patent and the '984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the "793 Patent") covering the formulation of the PEDMARK® product, which was listed in the Orange Book on or around April 17, 2023, and has an expiration date of July 2039. On May 11, 2023, we received written notice of CIPLA's Paragraph IV Certification as to the '793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the '793 Patent is invalid, unenforceable, and/or will not be infringed by CIPLA's ANDA Product. On July 27, 2023, we filed a Second Amended Complaint to assert the '793 Patent. CIPLA filed an Answer to the Second Amended Complaint on August 31, 2023. The suit is ongoing.

PEDMARQSI® (EU Brand name for PEDMARK®) received European Commission approval in June 2023 and was granted eight year of market exclusivity plus two years of data exclusivity in Europe under PUMA.

**Item 1A. Risk Factors.**

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 29, 2024 (the "Annual Report"), 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.**

*Insider Trading Arrangements and Policies*

During the quarter ended March 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulations S-K.

*Press Release*

On May 14, 2024, we issued a press release announcing our financial results for the quarter ended March 31, 2024. A copy of the news release is attached to this Quarterly Report as Exhibit 99.1. The press release is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references the press release.

**Item 6. Exhibits**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 10.1 <sup>1</sup>  | <a href="#">License and Supply Agreement, dated March 15, 2024, between Fennec Pharmaceuticals, Inc. and Norgine Pharma UK Limited.</a>  |
| 31.1               | <a href="#">Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>                             |
| 31.2               | <a href="#">Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>                             |
| 32.1               | <a href="#">Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a> |
| 99.1               | <a href="#">Press Release for Quarter Ended March 31, 2024 (filed herewith).</a>   |
| 101.INS*           | Inline XBRL Instance Document  |

|          |  |
|----------|--|
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document   |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document  |
| 104      | Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)   |
| 1.       | In accordance with Item 601(b)(10)(iv) of Regulation S-K, certain provisions and terms of this exhibit have been redacted. Fennec will provide an unredacted copy of the exhibit on a supplemental basis to the SEC or its staff upon request. |

**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: May 14, 2024

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

Date: May 14, 2024

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

FENNEC PHARMACEUTICALS INC  
CERTIFICATION

I, Rostislav Raykov, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2024 of Fennec Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the unaudited interim condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2024

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

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**FENNEC PHARMACEUTICALS INC.  
CERTIFICATION**

I, Robert Andrade, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2024 of Fennec Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the unaudited interim condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2024

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

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**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 March 31, 2024 (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: May 14, 2024

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

Date: May 14, 2024

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

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## FENNEC PHARMACEUTICALS REPORTS FIRST QUARTER 2024 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- ~ Achieved First Quarter 2024 Net Revenues of \$25.4 Million including \$18.0 million in licensing revenue from Norgine transaction ~
- ~ Executed Exclusive Licensing Agreement with Norgine to Commercialize PEDMARQS™ in Europe, Australia, and New Zealand ~
- ~ Amended PEDMARK® Permanent J-code 0208 Became Effective April 1, 2024 ~
- ~ Company Has Approximately \$51 Million in Cash, Cash Equivalents, and Investment Securities ~
- ~ Management to Host Conference Call Today at 8:30 a.m. ET ~

**Research Triangle Park, NC, May 14, 2024** – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the fiscal quarter ended March 31, 2024, and provided a business update.

"We made significant progress with our strategic plans to refocus our organizational efforts in the outpatient oncology community where PEDMARK® use has been endorsed by the NCCN in the adolescent and young adult (AYA) population. Effective April 1, CMS has amended our permanent J-code to specify the non-interchangeability of PEDMARK® with other formulations of sodium thiosulfate (STS). With the successful execution of the Norgine EU licensing agreement, we are well funded and confident in the significant market opportunity in front of us," said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals.

### Recent Developments and Highlights:

- Achieved PEDMARK net product revenue of approximately \$7.4 million in the first quarter of 2024 and total net revenues of \$25.4 million, which is inclusive of \$18.0 million in revenue from the Norgine transaction.
- Amended permanent J-Code, which became effective on April 1, 2024, now clearly specifies PEDMARK® from other formulations of sodium thiosulfate (STS).
- Announced execution of exclusive licensing agreement with Norgine to commercialize PEDMARQS™ in Europe, Australia, and New Zealand. Fennec received approximately \$43.2 million upfront and has the potential to receive up to approximately \$230 million in additional commercial and regulatory milestones, and double-digit tiered royalties.
- Within the first quarter, Fennec participated in eleven regional oncology conferences, as well as seven key scientific meetings, including the American Society of Pediatric Hematology/Oncology, the Community Oncology Alliance, the National Comprehensive Cancer Network, and the American Academy of Audiology annual conferences.

### Financial Results for the First Quarter 2024

- **Net Sales** – The company recorded net product sales of \$7.4 million and \$18.0 million in licensing revenue for total net sales of \$25.4 million for the three-month period ended March 31, 2024, compared to \$1.7 million in product sales and no licensing revenue for the same period in 2023. The Company recorded discounts and allowances against sales in the amount of \$2.1 million and cost of products sold of \$0.6 million for the three-month period ended March 31, 2024. For the same period in 2023, the Company recorded \$0.2 million in discounts and allowances and \$0.1 million in cost of goods sold.
- **Cash Position** – Cash and cash equivalents were \$51.2 million at March 31, 2024 and \$13.3 million at December 31, 2023. The increase in cash and cash equivalents between March 31, 2024, and December 31, 2023, is the result of cash outlays for operating expenses related to the promotion of our product, selling and marketing expenses and general and administrative expenses, which

were offset by cash inflows of approximately \$43.2 million from the Norgine deal. We anticipate that our cash, cash equivalents and investment securities as of March 31, 2024 will be sufficient to fund our planned operations for at least the next twelve months.

- **Selling and Marketing Expenses** – The Company recorded \$5.2 million in selling and marketing expenses for the period ended March 31, 2024, compared to \$2.5 million for the same period in 2023. The increase is largely related to increased payroll and additional marketing expenses in the comparable period.
- **General and Administrative (G&A) Expenses** – G&A expenses increased by approximately \$1.6 million over the same period in 2023 to \$5.8 million. There was a significant increase in consulting, and professional costs related to European pre-commercialization related expenses in the 2024 period over the comparable period.
- **Net Earnings** – Net income for the quarter ended March 31, 2024 was \$12.8 million (basic EPS \$0.47 per share, diluted EPS \$0.41), compared to a net loss of \$6.1 million (basic and diluted loss of \$0.23 per share) for the same period in 2023.

#### **Q1 2024 CONFERENCE CALL INFORMATION**

**Date:** Tuesday, May 14, 2024

**Time:** 8:30 a.m. Eastern Time

**Link:** <https://register.event.com/register/BI137d97d6710341398d6f17d0433dc5b8>

To access the conference call, please register using <https://register.event.com/register/BI137d97d6710341398d6f17d0433dc5b8>. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto [www.fennepharma.com](http://www.fennepharma.com) and proceed to the News & Events / Event Calendar page under the Investors & Media heading. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to listen to the webcast. A webcast replay of the conference call will also be archived on [www.fennecpharma.com](http://www.fennecpharma.com) for thirty days.

#### **Financial Update**

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements, which were prepared in accordance with U.S. generally accepted accounting principles. The complete unaudited condensed consolidated financial statements for the period ended March 31, 2024 and management's discussion and analysis of financial condition and results of operations will be available via [www.sec.gov](http://www.sec.gov) and [www.sedar.com](http://www.sedar.com). All values are presented in thousands unless otherwise noted.

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

|   | Three Months Ended |                   |
|---|--------------------|-------------------|
|   | March 31,<br>2024  | March 31,<br>2023 |
| <b>Revenue</b>  |                    |                   |
| PEDMARK product sales, net  | \$ 7,419           | \$ 1,677          |
| Licensing revenue   | 17,958             | —                 |
| <b>Total revenue</b>  | <u>25,377</u>      | <u>1,677</u>      |
| <b>Operating expenses:</b>  |                    |                   |
| Cost of products sold   | 550                | 95                |
| Research and development  | 3                  | 4                 |
| Selling and marketing   | 5,209              | 2,531             |
| General and administrative  | 5,872              | 4,317             |
| <b>Total operating expenses</b>                                     | <u>11,634</u>      | <u>6,947</u>      |
| <b>Income/(loss) from operations</b>                                | <u>13,743</u>      | <u>(5,270)</u>    |
| <b>Other (expense)/income</b>                                       |                    |                   |
| Unrealized foreign exchange loss                                    | (38)               | 9                 |
| Amortization expense  | (20)               | (72)              |
| Unrealized loss on securities                                       | (11)               | (30)              |
| Interest income   | 197                | 109               |
| Interest expense  | (1,034)            | (798)             |
| Total other expense   | <u>(906)</u>       | <u>(782)</u>      |
| <b>Net income/(loss)</b>  | <u>\$ 12,837</u>   | <u>\$ (6,052)</u> |
| <b>Basic net income/(loss) per common share</b>                     | <u>\$ 0.47</u>     | <u>\$ (0.23)</u>  |
| <b>Diluted net income/(loss) per common share</b>                   | <u>\$ 0.41</u>     | <u>\$ (0.23)</u>  |
| <b>Weighted-average number of common shares outstanding basic</b>   | <u>27,090</u>      | <u>26,559</u>     |
| <b>Weighted-average number of common shares outstanding diluted</b> | <u>31,136</u>      | <u>26,559</u>     |

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

|   | Unaudited<br>March 31,<br>2024 | Audited<br>December 31,<br>2023 |
|---|--------------------------------|---------------------------------|
| <b>Assets</b>   |                                |                                 |
| <b>Current assets</b>   |                                |                                 |
| Cash and cash equivalents   | \$ 51,184                      | \$ 13,269                       |
| Accounts receivable, net  | 10,274                         | 8,814                           |
| Prepaid expenses  | 4,488                          | 2,575                           |
| Inventory   | 2,064                          | 2,156                           |
| Other current assets  | 161                            | 44                              |
| <b>Total current assets</b>   | <u>68,171</u>                  | <u>26,858</u>                   |
| <b>Non-current assets</b>   |                                |                                 |
| Other non-current assets, net amortization  | 1,022                          | 6                               |
| <b>Total non-current assets</b>   | <u>1,022</u>                   | <u>6</u>                        |
| <b>Total assets</b>   | <u>\$ 69,193</u>               | <u>\$ 26,864</u>                |
| <b>Liabilities and stockholders' equity/(deficit)</b>   |                                |                                 |
| <b>Current liabilities:</b>   |                                |                                 |
| Accounts payable  | \$ 5,204                       | \$ 3,778                        |
| Accrued liabilities   | 4,363                          | 3,754                           |
| Operating lease liability - current   | 17                             | 21                              |
| Contract liability - Norgine  | 252                            | —                               |
| <b>Total current liabilities</b>  | <u>9,836</u>                   | <u>7,553</u>                    |
| <b>Long term liabilities</b>  |                                |                                 |
| Term loan   | 30,000                         | 30,000                          |
| PIK interest  | 1,617                          | 1,219                           |
| Debt discount   | (268)                          | (288)                           |
| Operating lease liability - net of current portion  | —                              | 2                               |
| Contract liability - Norgine  | 24,994                         | —                               |
| <b>Total long term liabilities</b>  | <u>56,343</u>                  | <u>30,933</u>                   |
| <b>Total liabilities</b>  | <u>66,179</u>                  | <u>38,486</u>                   |
| <b>Stockholders' equity/(deficit):</b>  |                                |                                 |
| Common stock, no par value; unlimited shares authorized; 27,105 shares issued and outstanding<br>(2023 -27,027) | 144,934                        | 144,307                         |
| Additional paid-in capital  | 63,245                         | 62,073                          |
| Accumulated deficit   | (206,408)                      | (219,245)                       |
| Accumulated other comprehensive income  | 1,243                          | 1,243                           |
| <b>Total stockholders' equity/(deficit)</b>   | <u>3,014</u>                   | <u>(11,622)</u>                 |
| <b>Total liabilities and stockholders' equity/(deficit)</b>   | <u>\$ 69,193</u>               | <u>\$ 26,864</u>                |

## Working Capital

| Working capital                    | Fiscal Period Ended |                   |
|------------------------------------|---------------------|-------------------|
| Selected Asset and Liability Data: | March 31, 2024      | December 31, 2023 |
| (U.S. Dollars in thousands)        |                     |                   |
| Cash and equivalents               | \$ 51,184           | \$ 13,269         |
| Other current assets               | 16,987              | 13,589            |
| Current liabilities                | 9,836               | 7,553             |
| Working capital                    | <u>\$ 58,335</u>    | <u>\$ 19,305</u>  |

  

| Selected Equity:                            | 208,179   | 206,380   |
|---|-----------|-----------|
| Common stock and additional paid in capital |           |           |
| Accumulated deficit                         | (206,408) | (219,245) |
| Stockholders' equity/(deficit)              | 3,014     | (11,622)  |

### About Cisplatin-Induced Ototoxicity

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

The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids or cochlear implants, which can be helpful for some, but do not reverse the hearing loss and can be costly over time. Infants and young children that are affected by ototoxicity at critical stages of development lack speech and language development and literacy, and older children and adolescents often lack social-emotional development and educational achievement.

### PEDMARK® (sodium thiosulfate injection)

PEDMARK® is the first and only U.S. Food and Drug Administration (FDA) approved therapy indicated to reduce the risk of ototoxicity associated with cisplatin treatment in pediatric patients with localized, non-metastatic, solid tumors. It is a unique formulation of sodium thiosulfate in single-dose, ready-to-use vials for intravenous use in pediatric patients.<sup>7</sup> PEDMARK is also the only therapeutic agent with proven efficacy and safety data with an established dosing paradigm, across two open-label, randomized Phase 3 clinical studies, the Clinical Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

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

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

### Indications and Usage

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

### Limitations of Use

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

## **Important Safety Information**

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

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

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

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

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

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

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

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

## **About Fennec Pharmaceuticals**

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK® to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and U.K. approval in October 2023. PEDMARK has received Orphan Drug Exclusivity in the U.S. For more information, please visit [www.fennecpharma.com](http://www.fennecpharma.com).

## **Forward Looking Statements**

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

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

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<sup>i</sup> Rybak L. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. *Current Opinion in Otolaryngology & Head and Neck Surgery*. 2007, Vol. 15: 364-369.

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

<sup>iii</sup> Bass JK, Knight KR, Yock TI, et al. Evaluation and Management of Hearing Loss in Survivors of Childhood and Adolescent Cancers: A Report from the Children's Oncology Group. *Pediatric Blood & Cancer*. 2016 Jul;63(7):1152-1162.