Table of Contents

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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

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

For the transition period from_____ to

Commission File Number: 001-32295

FENNEC PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(919) 636-4530
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

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 such files). YES ☒ NO ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price of the registrant's Common Shares as reported on the Nasdaq Capital Market on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) was $98,210,075 based upon a total of 17,625,103 shares held as of June 30, 2022 by persons believed to be non-affiliates of the registrant (for purposes of this calculation, all of the registrant's officers, directors and 10% owners known to the registrant are deemed to be affiliates of the registrant).

As of March 27, 2023, there were 26,411,520 shares of the registrant's Common Shares outstanding.

FENNEC PHARMACEUTICALS INC.
2022 FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

PART I

You are urged to read this Annual Report on Form 10-K ("Annual Report") in its entirety. This Annual Report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the projected results discussed in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those discussed below and in Item 1A, "Risk Factors," and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Caution Concerning Forward-Looking Statements."

"We," "our," "ours," "us," "Fennec," or the "Company," when used herein, refers to Fennec Pharmaceuticals Inc., a British Columbia corporation, and its wholly-owned subsidiary, Fennec Pharmaceuticals, Inc. a Delaware corporation.

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements", as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, "believes", "anticipates", "proposes", "plans", "expects", "intends", "may", and other similar expressions are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or other achievements to be materially different from any future results, performances or achievements expressed or implied by such forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the section entitled "Item 1A – Risk Factors" and those discussed in the section entitled "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Caution Concerning Forward-Looking Statements."

The successful commercialization of PEDMARK® is highly uncertain. Factors that will affect our success include the uncertainty of:

- Whether we will be able to continue to successfully market PEDMARK® while maintaining full compliance with applicable federal and state laws, rules and regulations;
- Whether our estimates of the size of the market for PEDMARK® to reduce the risk of ototoxicity associated with cisplatin use in pediatric patients will turn out to be accurate;
- Whether we will be able to locate pediatric patients diagnosed for cisplatin use;
- Whether patients will discontinue from the use of our drug at rates that are higher than historically experienced or are higher than we project;
- Whether the amount of PEDMARK® taken by patients changes over time and affects our results of operations;
- Whether we can market PEDMARK® on a profitable and cash flow positive basis;
- Whether payors will reimburse for our product at the price that we charge for the product;
- The ability of our third-party suppliers and contract manufacturers to maintain compliance with current Good Manufacturing Practices (cGMP);
- The ability of our distributor and the specialty pharmacies that distribute our product to maintain compliance with applicable law;
- Our ability to maintain compliance with applicable rules relating to our patient assistance programs and our contributions to 501(c)(3) organizations that support pediatric cancer patients;

- The scope of our intellectual property and the outcome of any future challenges or opposition to our intellectual property, and, conversely, whether any third-party intellectual property presents unanticipated obstacles for PEDMARK®;
- Whether we our successful in our lawsuit against CIPLA, Inc. opposing its abbreviated new drug application with the FDA to manufacture and sell a generic version of PEDMARK®;
- The impact on PEDMARK® of adverse changes in reimbursement and coverage policies from government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators, or the impact of pricing pressures enacted by industry organization, the federal government or the government of any state, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;
- Changes in the healthcare industry and the effect of political pressure from and actions by the President, Congress and/or medical professionals seeking to reduce prescription drug costs;
- The state of the economy generally and its impact on our business;
- Changes to the healthcare industry occasioned by any future changes in laws relating to the pricing of drug products, or changes in the healthcare industry generally;
- Our ability to complete any clinical trials and studies that we may undertake on a timely basis and within the budgets we establish for such trials and studies;
- The impact of the COVID-19 pandemic on our business or on the economy generally and whether COVID-19 will further affect the timing and costs of our currently ongoing and contemplated clinical trials; and
- Whether PEDMARK® can be successfully commercialized outside of the United States on a profitable basis;

Our current plans and objectives are based on assumptions relating to the continued commercialization of PEDMARK®. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements we have made herein, which reflect our views only as of the date of this report, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business

Overview

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

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

Further, 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 PEMARK in January 2023, which provides seven years of market exclusivity from its FDA approval on September 20, 2022 until September 20, 2029. We currently have three patents listed for PEDMARK® in the FDA's Orange Book. In March 2020, the United States Patent and Trademark Office, or USPTO,

allowed Patent No. 10,596,190 ("US '190"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using our PEDMARK® product. In September 2022, the USPTO issued Patent No. 11,291,728 ("728") and, in December 2022, the USPTO issued Patent No. 11,510,984 ('984) that covers PEDMARK® pharmaceutical formulation. The "728" and "984" patents will expire in 2039 and the "190" patent will expire in 2038. Additionally, in January 2023, the USPTO issued Notices of Allowance for an additional patent application that covers the PEDMARK® pharmaceutical formulation. We expect this additional U.S. patent to issue in Q1 or Q2 of 2023. This patent will expire in 2039, unless held invalid or unenforceable by a court of final jurisdiction. We are also pursuing additional patent applications in both the U.S. and internationally for PEDMARK®.

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 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. 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.

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.

European Marketing Authorization Application

In August 2018, the Pediatric Committee ("PDCO") of the European Medicines Agency ("EMA") accepted our pediatric investigation plan ("PIP") for sodium thiosulfate with the trade name Pedmarqsi for the condition of the prevention of

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

Third-Party Reimbursement

Sales of drug products depend in significant part on the availability of coverage and adequate reimbursement by third party payors, such as state and federal governments, including Medicare and Medicaid, managed care providers, private commercial insurance plans and pharmacy benefit management (PBM) plans. Decisions regarding the extent of coverage and the amount of reimbursement to be provided for PEDMARK® are expected to be made on a plan-by-plan, and in some cases, on a patient-by-patient basis. Particularly given the small size of the pediatric cancer population, our experience has been that securing coverage and appropriate reimbursement from third-party payors requires targeted education and highly skilled insurance navigation experts that have experience with rare and orphan disease launches and medical exception processes at insurance companies to provide patient coverage for important orphan disease therapies. To that end, we have engaged a dedicated team of reimbursement experts as well as a patient service center staffed with experienced personnel focused on ensuring that clinically-qualified patients have access to our product.

There can be no assurance, however, as to whether payors will continue to cover our product, and if so, at what level of reimbursement. In that regard, we have advised payors that we will provide free medication to support titration and confirm patient therapeutic benefit. Further, when necessary, we may provide patients with access to therapy at no charge while those patients are awaiting coverage decisions.

Intellectual Property

Patent Coverage

Patents are important to developing and protecting our competitive position. Our general policy is to seek patent protection in the United States, Europe, China, Japan, Canada and other jurisdictions as appropriate for our compounds and methods. U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest (priority) application was filed. The duration of foreign patents may vary in accordance with local law.

Our current patent portfolio reflects our strategy to expand and diversify our intellectual property to obtain protection for our PEDMARK® product. We currently wholly own two patent families directed to formulations that cover PEDMARK® and other potential future sodium thiosulfate formulations, and methods of using and manufacturing the same. Three US patents have been issued from these two families, and two of the issued patents (US '984 Patent; US '728 Patent) qualify for and have been listed in the FDA Orange Book. Our '363 issued patent covers a process of manufacture, which is a patent category that does not qualify for FDA orange book listing. One additional US pending patent application covering our PEDMARK formulation has been allowed (US App. No. 17/871,825), and on issuance will be listed in the FDA Orange Book. Six additional US patent applications are pending, three of which applications cover methods of using our PEDMARK® formulation and are eligible for listing on the FDA Orange Book if issued. The three other applications cover additional sodium thiosulfate formulations for potential future use. Additional applications from these families are pending in Australia, Brazil, Canada, China, the European Patent Office (EPO), Hong Kong, Indonesia, Israel, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Singapore, and Thailand. Applications from these patent families, where granted, valid, and enforceable, will expire in July 2039, exclusive of any patent term adjustment or extension.

We have exclusively in-licensed from Oregon Health & Science University ("OHSU") one patent family directed to the use of sodium thiosulfate to reduce the occurrence of ototoxicity. This family includes the granted US '190 Patent and

one pending US patent application. The US '190 Patent has been listed in the FDA Orange Book. The US '190 Patent will expire in January 2038, unless held invalid or unenforceable by a court of final jurisdiction. The pending US patent application, if granted, valid, and enforceable, will expire in November 2037, exclusive of any patent term adjustment or extension. In 2022, OHSU abandoned applications from this family in all ex-US jurisdictions.

Our success is significantly dependent on our ability to obtain and maintain patent protection for PEDMARK®, both in the United States and abroad. Our patent position and proprietary rights are subject to various risks and uncertainties. Please read the "Risk Factors" in Item 1A of this Annual Report for information about certain risks and uncertainties that may affect our patent position and proprietary rights.

We also rely upon unpatented confidential information to remain competitive. We protect such information principally through confidentiality agreements with our employees, consultants, outside scientific collaborators, and other advisers. In the case of our employees, these agreements also provide, in compliance with relevant law, that inventions and other intellectual property conceived by such employees during their employment shall be our exclusive property.

FDA Orange Book Listings

On April 5, 2022, the USPTO issued U.S. Patent No. 11,291,728 (the "US '728 Patent") that covers the PEDMARK® pharmaceutical formulation. On November 9, 2022, the USPTO issued U.S. Patent No. 11,510,984 (the "US '984 Patent") that also covers the PEDMARK® pharmaceutical formulation. On January 23, 2023, the USPTO issued a Notice of Allowance for an additional patent application (US App. No. 17/871,825) that covers the PEDMARK® pharmaceutical formulation. We expect this application to issue as a patent in Q2 of 2023. We own three additional pending US patent applications directed to methods of treatment using the PEDMARK® formulation. These patents where granted will expire in July 2039, exclusive of patent term adjustment and/or extension, unless held invalid or unenforceable by a court of final jurisdiction.

We have exclusively licensed from OHSU U.S. Patent No. 10,596,190 ("the US '190 Patent") and a pending US patent application directed to a method of reducing ototoxicity using sodium thiosulfate. The US '190 Patent will expire in January 2038, unless held invalid or unenforceable by a court of final jurisdiction. The pending US patent application, if granted, valid, and enforceable, will expire in November 2037, exclusive of any patent term adjustment or extension, unless held invalid or unenforceable by a court of final jurisdiction.

On approval of PEDMARK®, we listed the US '190 Patent and US '728 Patent in the United Stated Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. The US'984 Patent was listed in the FDA Orange Book on December 14, 2022, following its issuance. A third formulation application, USSN 17/871,825 has been allowed by the U.S. Patent Office and will be listed when issued. If issued, the three additional US pending patent applications owned by us and the exclusively licensed pending US patent application owned by OHSU are eligible for listing in the FDA Orange Book.

Orphan Drug Exclusivity

We were granted Orphan Drug Exclusivity ("ODE") in January 2023 for the use of PEDMARK® in the indication to reduce the risk of ototoxicity, or hearing loss, associated with cisplatin use in pediatric patients one month of age and older with localized, non-metastatic solid tumors. The ODE designation is effective as of September 20, 2022, and provides us with seven years of market exclusivity in the PEDMARK® indication pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360cc). We plan to pursue PUMA upon approval of the MAA, which would allow for 10 years of market exclusivity upon PUMA approval.

Hope Medical Enterprises, Inc. Inter Partes Review Challenges

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

ingredient in our PEDMARK® product. The US ‘190 Patent was issued on March 24, 2020. The US ‘363 Patent was issued on October 6, 2020.

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

Further, in May 2022, the PTAB granted Hope Medical’s Petition to Institute the IPR against the ‘363 Patent. During the ‘363 Patent IPR, we disclaimed the ‘363 Patent claims directed to the anhydrous morphic form of STS, and filed a Motion to Amend the remaining method of manufacture claims. On December 14, 2022, we filed a Revised Motion to Amend the remaining claims in the ‘363 Patent. We expect a decision in the ‘363 IPR in May 2023, which can be appealed by the losing party.

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

CIPLA ANDA 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 US ‘190 Patent, expiration date January 2038; and our US 11,291,728 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. 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. 3:23-cv-00123), for infringement of the ‘190 Patent and the ‘728 Patent. The suit is ongoing.

We plan to pursue PUMA upon approval of the MAA, which would allow for 10 years of market exclusivity in Europe upon PUMA approval.

Our success is significantly dependent on our ability to obtain and maintain patent protection for PEDMARK®, both in the United States and abroad. Our patent position and proprietary rights are subject to various risks and uncertainties. Please

read the “Risk Factors” in Item 1A of this Annual Report for information about certain risks and uncertainties that may affect our patent position and proprietary rights.

We also rely upon unpatented confidential information to remain competitive. We protect such information principally through confidentiality agreements with our employees, consultants, outside scientific collaborators, and other advisers. In the case of our employees, these agreements also provide, in compliance with relevant law, that inventions and other intellectual property conceived by such employees during their employment shall be our exclusive property.

Manufacturing and Supply

We are licensed as a virtual drug manufacturer, which means that we have no in-house manufacturing capacity and we are obligated to rely on contract manufacturers and packagers. We have no plans to build or acquire the manufacturing capability needed to manufacture PEDMARK®, and we expect that PEDMARK® will be prepared by contractors with suitable capabilities for these tasks and that we will enter into appropriate supply agreements with these contractors at appropriate times in the development and commercialization of our product. Because we will use contractors to manufacture and supply our product, we will be reliant on such contractors. Further, the contractors selected would have to be inspected by the FDA and found to be in substantial compliance with federal regulations in order for an application for one of our drug candidates to be approved, and there can be no assurance that the contractors we select would pass such an inspection.

We have entered into agreements with a supplier of the active pharmaceutical ingredient (API) contained in PEDMARK® for future requirements and we have contracted with third-party contract manufacturers who are manufacturing PEDMARK® vials for us.

Any significant change that we make for PEDMARK® must be approved by the FDA in a supplemental new drug application (sNDA). If the manufacturing plan and data are insufficient, any sNDA we submit will not be approved. Before an sNDA can be approved, our manufacturers must also demonstrate compliance with FDA’s current Good Manufacturing Practices (cGMPs) regulations and policies. Further, even if we receive approval of any sNDAs for PEDMARK®, if our manufacturers do not follow cGMPs in the manufacture of our product, it may delay product launches or shipments and adversely affect our business.

Since we contract with third parties to manufacture our product, our contract manufacturers are required to comply with all applicable environmental laws and regulations that affect the manufacturing process. As a result, we do not believe that we will have any significant direct exposure to environmental issues.

Corporate Relationships

License Agreement with Oregon Health & Science University

On February 20, 2013, we 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, we negotiated an amendment ("Amendment 1") to the OHSU Agreement, which expands our exclusive license to include the use of N-acetylcysteine as a standalone therapy and/or in combination with STS 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 us or 8 years, whichever is later. PEDMARK® is currently protected by methods of use patent that we exclusively license from OHSU in the '190 patent that is set to expire in the United States in 2038. The OHSU Agreement is terminable by either us or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. We also have 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.

COVID-19

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

Competition

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors are many in number and include major and mid-sized pharmaceutical and biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies. Now that PEDMARK® has regulatory approval for sale, it will compete on the basis of drug efficacy, safety, patient convenience, reliability, ease of manufacture, price, marketing, distribution, and patent protection, among other variables. Our competitors may develop technologies or drugs that are more effective, safer or more affordable than PEDMARK®.

We are not aware of any commercially available agents that reduce the incidence of hearing loss associated with the use of platinum-based anti-cancer agents, which is the purpose of PEDMARK®. However, there are several potential competitive agents with activity in preclinical or limited clinical settings. These include: D-methionine, an amino acid that has been shown to protect against hearing loss in experimental settings but was demonstrated to be inferior to PEDMARK® in comparative studies; SPI-3005, an oral agent primarily being developed by Sound Pharmaceuticals for noise and age-related hearing loss but in early Phase II trials for chemotherapy related hearing loss, which mimics glutathione peroxidase and induces the intracellular induction of glutathione; N-acetylcysteine and amifostine, which have shown effectiveness (but less than PEDMARK®) in experimental systems; and Vitamin E, salicylate and tiopronin, which have all demonstrated moderate activity in rat models to protect against cisplatin-induced ototoxicity, but no clinical trials have been completed, and DB-020, a clinical stage candidate in an ongoing Phase1b trial being developed by Decibel Therapeutics. Cochlear implants, which are small electronic devices that are surgically placed in the inner ear to assist with certain types of deafness, are utilized to offer some relief for hearing loss associated with the use of platinum-based anti-cancer agents, but are often suboptimal.

Finally, we are aware that sodium thiosulfate has been available from compounding pharmacies for many years and may remain available, even though we have obtained FDA approval of PEDMARK®. Compounded sodium thiosulfate is likely to be substantially less expensive than PEDMARK®. The Food and Drug Administration Modernization Act of 1997 included a new section, which clarified the status of pharmacy compounding under Federal law. Under Section 503A, drug products that are lawfully compounded by a pharmacist or physician for an individual patient may be entitled to exemptions from three key provisions of the FDCA: (1) the adulteration provision of section 501(a)(2)(B) (concerning FDA's cGMP regulations); (2) the misbranding provision of section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) the new drug provision of section 505 (concerning the approval of drugs under new drug or abbreviated new drug applications).

To qualify for these statutory exemptions, a compounded drug product must satisfy several legal requirements. One of these requirements restricts the universe of bulk drug substances that a compounder may use. Specifically, every bulk drug

substance used in compounding: (1) must comply with an applicable and current USP or NF drug monograph, if one exists, as well as the current USP chapters on pharmacy compounding; (2) if such a monograph does not exist, the bulk drug substance must be a component of an FDA-approved drug; or (3) if a monograph does not exist and the bulk drug substance is not a component of an FDA-approved drug, it must appear on a list of bulk drug substances that may be used in compounding (i.e., the "Section 503A bulk substances list 1"). While the advertising provisions in Section 503A were ruled unconstitutional in part in the United States by the Supreme Court in 2002, the FDA, since 2013, has aggressively regulated and exercised oversight over the practice of pharmacy compounding following the compounding incident at the New England Compounding Center in Massachusetts that sickened hundreds and killed over 60 individuals.

In 2013, Congress removed the unconstitutional advertising provisions in Section 503A when it passed the Drug Quality and Security Act of 2013 (DQSA), Title I (The Compounding Quality Act). The DQSA also created "outsourcing facilities" under Section 503B of the Federal Food, Drug, and Cosmetic Act, which are drug compounders that voluntarily register with FDA and may produce compounded formulations for office use (at least one of which must be sterile), but must comply with FDA's cGMP regulations and other requirements set forth in Section 503B. Section 503B outsourcing facilities may also only compound from bulk substances if the product is on FDA's drug shortage list, or the substance is on FDA's Section 503B list of bulk substances that may be used in compounding (i.e., the Section 503B bulk substances list 1").

While the FDA has been aggressively enforcing Section 503A since its re-enactment, compounders may still compound "near copies" (but not "essentially copies") of approved drug products, under Section 503A, so long as the prescriber makes a change to the compounded formulation that produces for that patient a significant difference between the commercially available drug and the compounded version. Compounders may also copy commercially available products if they do not do so in "regular or inordinate amounts." In January 2018, FDA published a Final Guidance document titled, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act." This Final Guidance sets forth FDA's enforcement policy concerning those compounders that make essentially copies of commercially available drug products. FDA has defined the term "regular or inordinate" in the Final Guidance to mean: "a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances." FDA has further stated it will not take enforcement action, considering all the facts and circumstances, against a compounder that compounds less than four "essentially copies" of a commercially available drug product in a calendar month.

Factors affecting competition generally

In general, our ability to compete depends in large part upon:

- our ability to obtain regulatory approvals for our drug candidates outside the U.S.;
- the demonstrated efficacy, safety and reliability of our drug candidates;
- the timing and scope of regulatory approvals;
- product acceptance by physicians and other health care providers;
- the willingness of payors to reimburse for our product;
- protection of our proprietary rights and the level of generic competition;
- our ability to supply commercial quantities of our product to the market;
- our ability to obtain reimbursement from private and/or public insurance entities for product use in approved indications;
- our ability to recruit and retain skilled employees; and

• the availability of capital resources to fund our development and commercialization activities, including the availability of funding from the federal government.

Government Regulation

The production and manufacture of our product and our research and development activities are subject to significant regulation for safety, efficacy and quality by various governmental authorities around the world. Before new pharmaceutical products may be sold in the U.S. and other countries, clinical trials of the product must be conducted, and the results submitted to appropriate regulatory agencies for approval. Clinical trial programs must establish efficacy, determine an appropriate dose and regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. In the U.S., the results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a Biologics License Application or a NDA. In response to these submissions, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. Similar submissions are required by authorities in other jurisdictions who independently assess the product and may reach the same or different conclusions.

The receipt of regulatory approval often takes a number of years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. On occasion, regulatory authorities may require larger or additional studies, leading to unanticipated delay or expense. Even after initial approval from the FDA or other regulatory agencies has been obtained, further clinical trials may be required to provide additional data on safety and effectiveness. Additional trials are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. Furthermore, the FDA and other regulatory agencies require companies to disclose clinical trial results. Failure to disclose such results within applicable time periods could result in penalties, including civil monetary penalties.

In Canada, these activities are subject to regulation by Health Canada's Therapeutic Products Directorate ("TPD") and the rules and regulations promulgated under the Food and Drug Act. In the United States, drugs and biological products are subject to regulation by the FDA. The FDA requires licensing of manufacturing and contract research facilities, carefully controlled research and testing of products and governmental review and approval of results prior to marketing therapeutic products. Additionally, the FDA requires adherence to current Good Laboratory Practices ("cGLP") as well as current Good Clinical Practices ("cGCP") during clinical testing and cGMP and adherence to labeling and supply controls. The systems of new drug approvals in Canada and the United States are substantially similar and are generally considered to be among the most rigorous in the world.

Generally, the steps required for drug approval in Canada and the United States, specifically in cancer related therapies, include:

- *Preclinical Studies*: Preclinical studies, also known as non-clinical studies, primarily involve evaluations of pharmacology, toxic effects, pharmacokinetics and metabolism of a drug in animals to provide evidence of the relative safety and bioavailability of the drug prior to its administration to humans in clinical studies. A typical program of preclinical studies takes 18 to 24 months to complete. The results of the preclinical studies as well as information related to the chemistry and comprehensive descriptions of proposed human clinical studies are then submitted as part of the Investigational New Drug Application ("IND") to the FDA, a Clinical Trial Application to the TPD, or similar submission to other foreign regulatory bodies. This is necessary in Canada, the United States and most other countries prior to undertaking clinical studies. Additional preclinical studies are conducted during clinical development to further characterize the toxic effects of a drug prior to submitting a marketing application.

- *Phase 1 Clinical Trials*: Most Phase 1 clinical trials take approximately one year to complete and are usually conducted on a small number of healthy human subjects to evaluate the drug's safety, tolerability and pharmacokinetics. In some cases, such as cancer indications, Phase 1 clinical trials are conducted in patients rather than healthy volunteers.

- *Phase 2 Clinical Trials*: Phase 2 clinical trials typically take one to two years to complete and are generally carried out on a relatively small number of patients, generally between 15 and 50, in a specific setting of targeted disease

or medical condition, in order to provide an estimate of the drug's effectiveness in that specific setting. This phase also provides additional safety data and serves to identify possible common short-term side effects and risks in a somewhat larger group of patients. Phase 2 testing frequently relates to a specific disease, such as breast or lung cancer. Some contemporary methods of developing drugs, particularly molecularly targeted therapies, do not require broad testing in specific diseases, and instead permit testing in subsets of patients expressing the particular marker. In some cases, such as cancer indications, the company sponsoring the new drug may submit a marketing application to seek accelerated approval of the drug based on evidence of the drug's effect on a "surrogate endpoint" from Phase II clinical trials. A surrogate endpoint is a laboratory finding or physical sign that may not be a direct measurement of how a patient feels, functions or survives, but is still considered likely to predict therapeutic benefit for the patient. If accelerated approval is received, the company sponsoring the new drug must continue testing to demonstrate that the drug indeed provides therapeutic benefit to the patient.

- *Phase 3 Clinical Trials*: Phase 3 clinical trials typically take two to four years to complete and involve tests on a much larger population of patients suffering from the targeted condition or disease. These studies involve conducting controlled testing and/or uncontrolled testing in an expanded patient population, numbering several hundred to several thousand patients, at separate test sites, known as multi-center trials, to establish clinical safety and effectiveness. These trials also generate information from which the overall benefit-risk relationship relating to the drug can be determined and provide a basis for drug labeling. Phase 3 trials are generally the most time consuming and expensive part of a clinical trial program. In some instances, governmental authorities, such as the FDA, will allow a single Phase 3 clinical trial to serve as a pivotal efficacy trial to support a marketing application.

- *Marketing Application*: Upon completion of Phase 3 clinical trials, the pharmaceutical company sponsoring the new drug assembles all the chemistry, preclinical and clinical data and submits it to the TPD or the FDA as part of a New Drug Submission in Canada or a NDA in the United States. The marketing application is then reviewed by the applicable regulatory body for approval to market the product. The review process generally takes twelve to eighteen months.

Any clinical trials that we conduct may not be successfully completed, either in a satisfactory time period or at all. The typical time periods described above may vary substantially and may be materially longer. In addition, the FDA and its counterparts in other countries have considerable discretion to discontinue trials if they become aware of any significant safety issues or convincing evidence that a therapy is not effective for the indication being tested. It is possible the FDA and its counterparts in other countries may not (i) allow clinical trials to proceed at any time after receiving an IND, (ii) allow further clinical development phases after authorizing a previous phase, or (iii) approve marketing of a drug after the completion of clinical trials.

While European, U.S. and Canadian regulatory systems require that medical products be safe, effective, and manufactured according to high quality standards, the drug approval process in Europe differs from that in the United States and Canada and may require us to perform additional preclinical or clinical testing regardless of whether FDA approval has been obtained. The amount of time required to obtain necessary approvals may be longer or shorter than that required for FDA or TPD approval. European Union Regulations and Directives generally classify health care products either as medicinal products, medical devices or in vitro diagnostics. For medicinal products, marketing approval may be sought using either the centralized procedure of the European Agency for the Evaluation of Medicinal Products ("EMEA"), or the decentralized, mutual recognition process. The centralized procedure, which is mandatory for some biotechnology derived products, results in an approval recommendation from the EMEA to all member states, while the European Union mutual recognition process involves country by country approval.

Other Regulatory Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, annual establishment registration, product listing, user fees, compliance with requirements regarding cGMP, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and adverse drug experience monitoring and reporting with the product. After approval, most changes to the approved product labeling, such as adding new indications, are subject to prior FDA review and approval. Also, any post-approval changes in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product

are subject to FDA review and approval. Any such changes that have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product may not be implemented until 30 days after the FDA receives a supplement for the change. All manufacturing facilities, as well as records required to be maintained under FDA regulations, are subject to inspection or audit by the FDA. In addition, manufacturers generally are required to pay annual user fees for approved products and a user fee for the submission of each new or supplemental application.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-approval testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a REMS from drug manufacturers to manage a known or potential serious risk associated with the drug and to ensure that the benefits of a drug outweigh its risks. Examples of a REMS include, but are not limited to, a Medication Guide, a patient package insert to help mitigate a serious risk of the drug, and a communication plan to healthcare providers to support the implementation of an element of the REMS.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and register or obtain permits or licenses in states where they do business, and are subject to periodic unannounced inspections by the FDA and state regulatory authorities with jurisdiction over their activities to determine compliance with regulatory requirements. A drug manufacturer is responsible for ensuring that its third-party contractors operate in compliance with applicable laws and regulations including the cGMP regulation. The failure of a drug manufacturer or any of its third-party contractors to comply with federal or state laws or regulations may subject the drug manufacturer to possible legal or regulatory action, such as an untitled letter, warning letter, recall, suspension of manufacturing or distribution or both, suspension of state permit or license, seizure of product, import detention, injunctive action, and civil and criminal penalties.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require a drug manufacturer to conduct investigations and implement appropriate corrective actions to address any deviations from cGMP requirements and impose reporting and documentation requirements upon the manufacturer and any third-party contractors (including contract manufacturers and laboratories) involved in the manufacture of a drug product. Accordingly, manufacturers must continue to expend significant time, money and effort to maintain and ensure ongoing cGMP compliance and to confirm and ensure ongoing cGMP compliance of their third-party contractors.

Once an approval is granted, the FDA may withdraw the approval if, among other things, there is information that the drug is unsafe for use under the approved conditions of use; new information or evidence that, evaluated together with evidence available to the FDA at the time of approval, shows that the drug is not shown to be safe for use under the approved conditions of use; new information that, evaluated together with the evidence available to the FDA at the time of approval, shows there is a lack of substantial evidence of effectiveness; the approved application contains an untrue statement of material fact; or that the required patient information was not submitted within 30 days after receiving notice from the FDA of the failure to submit such information. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety and risk information; imposition of a post-market study requirement to assess new safety risks; or implementation of a REMS that may include distribution or other restrictions.

The FDA closely regulates drug advertising and promotional activities, including promotion of an unapproved drug, direct-to-consumer advertising, dissemination of scientific information about a drug not on the approved labeling, off-label promotion, communications with payors and formulary committees, industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media. A company's product claims must be true and not misleading, provide fair balance, provide adequate risk information, and be consistent with the product labeling approved by the FDA. Failure to comply with these requirements can lead to legal or regulatory actions including, among other things, warning letters, corrective advertising, injunction, violation and related penalties under the False Claims Act and can result in reputational and economic harm.

Physicians may prescribe FDA-approved drugs for uses that are not described in the product's labeling and that differ from those uses tested by the manufacturer. Such off-label uses occur across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the

behavior of physicians in their choice of treatments for their individual patients. The FDA does, however, regulate manufacturers' communications about their drug products and interprets the Federal Food, Drug, and Cosmetic Act ("FFDCA") to prohibit pharmaceutical companies from promoting their FDA-approved drug products for uses that are not specified in the FDA-approved labeling. Companies that market drugs for off-label uses have been subject to warning letters, related costly litigation, criminal prosecution, and civil liability under the FFDCA and the False Claims Act.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), as amended by the Drug Supply Chain Security Act, which regulates the distribution of drug and drug samples at the federal level, and sets minimum standards for the registration and regulation of wholesale drug distributors by the states.

Good Clinical Practices

The FDA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Clinical Practices, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA and other regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If our study sites fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications.

Good Manufacturing Practices

The FDA and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacture of pharmaceutical and biological products prior to approving a product. If, after receiving approval from regulatory agencies, a company makes a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required. All facilities and manufacturing techniques that may be used for the manufacture of our product must comply with applicable regulations governing the production of pharmaceutical products known as Good Manufacturing Practices.

Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. If a product which has an orphan drug designation subsequently receives the first FDA approval for that drug for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other application submitted by a different applicant to market the same drug for the same indication for a period of seven years following marketing approval, except in certain very limited circumstances, such as if the later product is shown to be clinically superior to the approved product with orphan drug exclusivity. Legislation similar to the Orphan Drug Act has been enacted in other countries, including within the European Union.

Pediatric Marketing Use Authorization

The PUMA approval is typically granted by the European Commission, based on a review by the European Medicines Agency, and is intended exclusively for pediatric (patients under 18 years of age) use. Such PUMA approval is ultimately valid in all countries within the European Economic Area (which excludes the United Kingdom as of February 1, 2020).

The PUMA was introduced by the EU Pediatric Regulation for medicines that are:

- Normally contain an already authorized active ingredient;
- Are no longer covered by a supplementary protection certificate ("SPC") or a patent that qualifies for a SPC; and
- Are to be exclusively developed for use in children.

The PUMA process was established to make it more efficient for pharmaceutical companies to invest in the development of drugs for children. PUMA drugs receive 8 plus 2 years of regulatory data and marketing protection and the applications are, in part, exempt from fees. The regulatory protection does not prevent off-label use of other drugs with the same active substance and indication for adults, nor pharmacy compounding.

Other Laws

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or approved methods of using the product. Upon approval of a drug, each of the patents listed in the application for the drug are then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity (NCE), which is a drug product that contains an active moiety that has never been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. A drug may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for the previously

approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. During this period of exclusivity, FDA cannot approve an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there cannot be a Paragraph IV certification, and, thus, no ANDA can be filed before the expiration of the exclusivity period.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2), or 505(b)(2), NDA, which enables the applicant to rely, in part, on FDA's previous approval of a similar product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's prior findings of safety and effectiveness or published literature is scientifically appropriate, it may eliminate the need to conduct certain pre-clinical or clinical studies of the new product.

The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. A Section 505(b)(2) NDA may be eligible for three years of marketing exclusivity to the same extent that a Section 505(b)(1) NDA is.

Abbreviated New Drug Applications

Generic drugs may enter the market after the approval of an ANDA. The ANDA development process typically does not require new pre-clinical or clinical studies, but it does typically require one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved brand name reference listed drug. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the approved listed product containing the same active ingredient. Bioavailability is a measure of the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. A demonstration of bioequivalence means that the rate and extent of absorption of the ANDA drug is not significantly different from the rate and extent of absorption of the brand name reference listed drug when administered at the same molar dose under similar experimental conditions.

As noted above, generic drug products are generally introduced to the marketplace at the expiration of patent protection and non-patent market exclusivity for the reference listed drug. However, if an ANDA applicant is the first ANDA applicant to submit an ANDA containing a Paragraph IV certification, that ANDA may be eligible for a period of generic marketing exclusivity on approval. This exclusivity, which under certain circumstances must be shared with other ANDA applicants with Paragraph IV certifications, lasts for 180 days, during which the FDA cannot grant final approval to other ANDA sponsors of an application for a generic equivalent to the same reference drug. Under certain circumstances, eligibility for 180-day exclusivity may be forfeited.

Various types of changes to an approved ANDA must be requested in a prior approval supplement. In addition, some changes may only be approved after new bioequivalence studies are conducted or other requirements are satisfied. In addition, the ANDA applicant must demonstrate that manufacturing procedures and operations conform to FDA cGMP requirements. Facilities, procedures, operations, and/or testing of products are subject to periodic inspection by the FDA and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and inspections to determine whether the systems and processes are in compliance with cGMP and other FDA regulations.

There are also user fees for ANDA applicants, sponsors, and manufacturers. For fiscal year 2022, the application fees are $225,712 per ANDA application and the facility fees are $195,012 per domestic finished dosage form facility, $210,012 per foreign finished dosage form facility, $42,557 per domestic active pharmaceutical ingredient facility, and $57,557 per foreign active pharmaceutical ingredient facility. In addition, there is a new annual program fee based on the size of the generic drug applicant. These user fees typically increase each fiscal year.

Other regulatory requirements

In addition to regulation by the FDA and certain state regulatory agencies, we are also subject to a variety of foreign regulations governing clinical trials and the marketing of other products. Outside of the United States, our ability to market our product depends upon receiving a marketing authorization from the appropriate regulatory agencies. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our product if the appropriate regulatory agency is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Under the European Union regulatory system, applications for drug approval may be submitted either in a centralized or decentralized manner. Under the centralized procedure, a single application to the European Medicines Agency leads to an approval granted by the European Commission which permits marketing of the product throughout the European Union. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not comply with requirements for the centralized procedure. Under the decentralized procedure, the holders of national marketing authorization in one of the countries within the European Union may submit further applications to other countries within the European Union, who will be requested to recognize the original authorization based on an assessment report provided by the country in which marketing authorization is held.

Pharmaceutical pricing and reimbursement

In both United States and foreign markets, our ability to commercialize our product successfully, and to attract commercialization partners for our product, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as Medicare and Medicaid, managed care organizations, private commercial health insurers and PBMs. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic or other studies in order to further demonstrate the value of our product. Even with the availability of such studies, our product may be considered less safe, less effective or less cost-effective than alternative products, and third-party payors may not provide coverage and reimbursement for our drug candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business, including the Patient Protection and Affordable Care Act of 2010 (the “Affordable Care Act”). In fact, there continue to be efforts in Congress to revise the Affordable Care Act and replace it with another law. As a result, there is great uncertainty as to what changes will be made to United States healthcare laws and there can be no assurance how changes to those laws may affect our business.

We anticipate that in the United States, Congress, state legislatures, and private sector entities will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures could include:

- controls on government-funded reimbursement for drugs;

- mandatory rebates or additional charges to manufacturers for their products to be covered on Medicare Part D formularies;

- controls on healthcare providers;

- controls on pricing of drug products, including the possible reference of the pricing of United States drugs to non-United States drug pricing for the same product;

- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

- reform of drug importation laws;
- entering into contractual agreements with payors; and
- expansion of use of managed-care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted may have a material adverse effect on our business prospects.

Further, the pricing of drug products generally, and particularly the pricing of orphan drugs, has recently received scrutiny from the press, and from members of Congress in both parties. The impact of this scrutiny on us and on the pricing of orphan drugs and other drug products generally cannot be determined with any certainty at this time.

Orphan Drug Exclusivity and Pediatric Exclusivity Designation

Some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983 (ODA), the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, Orphan Drug Designation must be requested before submitting an application for marketing approval. An Orphan Drug Designation does not shorten the duration of the regulatory review and approval process. The grant of an Orphan Drug Designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies. If a product which has been granted Orphan Drug Designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to an orphan drug exclusivity period, which means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as where an alternative product demonstrates clinical superiority to the product with orphan exclusivity. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

The orphan drug exclusivity contained in the ODA has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community, and a recent proposed change to the ODA would limit the availability of the benefits of the act for drugs that treat more than 200,000 individuals in the United States. There can be no assurance that the exclusivity granted in ODA to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our product, if approved.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five-year and three-year non-patent and seven-year orphan exclusivities. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied. If the FDA determines that information relating to the use of the new drug in the pediatric population may produce health benefits in the population, the clinical study is deemed to fairly respond to the FDA's request and the reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application relying on the NDA sponsor's data.

The European Orphan Drug Regulation is considered for drugs intended to diagnose, prevent or treat a life-threatening or very serious condition afflicting five or fewer per 10,000 people in the EU, including compounds that for serious and chronic conditions would likely not be marketed without incentives due to low market return on the sponsor's development

investment. The medicinal product considered should be of significant benefit to those affected by the condition. Benefits of being granted Orphan Medicinal Product Designation are significant, including eight years of data exclusivity, two years of marketing exclusivity and a potential one-year extension of both. The EU Community and Member States may not accept or grant for ten years a new marketing authorization or application for another drug for the same therapeutic indication as the orphan drug, although the ten-year period can be reduced to six years if, after the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of the marketing exclusivity. A supplementary protection certificate may extend the protection six months beyond patent expiration if that is later than the orphan drug exclusivity period. To apply for the supplementary protection, a pediatric investigation plan, or PIP, must be included in the market application. In Europe all drugs now seeking marketing authorization need to have a PIP agreed with the European Medicines Agency (EMA) before it can be approved, even if it is a drug being developed specifically for a pediatric indication. If a product is developed solely for use in the pediatric population, then a Pediatric Use Marketing Authorization, or PUMA, may provide eight years of data exclusivity and ten years of marketing exclusivity.

Breakthrough Therapy Designation

Breakthrough therapy designation by the FDA is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the fast track program features (see below for more details on fast track designation), as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance. Actions taken to expedite development may include the following actions, as appropriate:

- holding meetings with the sponsor and review team throughout the development of the drug;

- providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as possible;

- taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;

- assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-discipline members of the review team (i.e., clinical, pharmacology-toxicology, chemistry, manufacturing and control (CMC), compliance) for coordinated internal interactions and communications with the sponsor through the review division's Regulatory Health Project Manager; and

- involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review.

Fast Track Designation and Accelerated Approval

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or

other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under FDA policies, a drug candidate is eligible for priority review, or review within a six to eight-month time frame from the time a complete NDA is submitted, if the drug candidate is intended for the treatment, diagnosis, or prevention of a serious or life-threatening condition, demonstrates the potential to address an unmet medical need, or provides a significant improvement compared to marketed drugs.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical trial. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

Anti-Kickback, False Claims Laws & the Prescription Drug Marketing Act

In addition to FDA restrictions on marketing of drug products, other state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and patients, prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal

anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

The Centers for Medicare & Medicaid Services (CMS) has issued a final rule that requires manufacturers of approved prescription drugs to collect and report information on payments or transfers of value to physicians, physician assistants, certain types of advanced practice nurses and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The information reported each year is made publicly available on a searchable website. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products, to report gifts and payments to individual physicians in these states and to report certain pricing information, including price increases. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the United States Prescription Drug Marketing Act (PDMA), a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act (DSCSA), has imposed new “track and trace” requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. The DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to eventually establish an electronic interoperable prescription product to system to identify and trace certain prescription drugs distributed in the United States and preempts existing state drug pedigree laws and regulations on this topic. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers, although FDA regulations addressing wholesale distributors and third party logistics providers have not yet been promulgated. We serialize our product at both the package and homogeneous case level, pass serialization and required transaction information to our customers, and believe that we comply with all such requirements.

Government Programs for Marketed Drugs

Medicaid, the 340B Drug Pricing Program, and Medicare

Federal law requires that a pharmaceutical manufacturer, as a condition of having its products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. This federal requirement is effectuated through a Medicaid drug rebate agreement between the manufacturer and the Secretary of Health and Human Services. CMS administers the Medicaid drug rebate agreements, which provide, among other things, that the drug manufacturer will pay rebates to each state Medicaid agency on a quarterly basis and report certain price information on a monthly and quarterly basis. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs. For innovator products, that is, drugs that are marketed under approved NDAs, the basic rebate amount is the greater of 23.1% of the average manufacturer price (“AMP”) for the quarter or the difference between such AMP and the best price for that same quarter. The AMP is the weighted average of prices paid to the manufacturer (1) directly by retail community pharmacies and (2) by wholesalers for drugs distributed to retail community pharmacies. The best price is essentially the lowest price available to non-governmental entities. Innovator products are also subject to an additional rebate that is based on the amount, if any, by which the product’s current AMP has increased over the baseline AMP, which is the AMP for the first full quarter after launch, adjusted for inflation. To date, the rebate amount for a drug has been capped at 100% of the AMP; however, effective January 1, 2024, this cap will be eliminated, which means that a manufacturer could pay a rebate amount on a unit of the drug that is greater than the average price the manufacturer receives for the drug. For non-innovator products, generally generic drugs marketed under approved abbreviated new drug applications, the basic rebate amount is 13% of the AMP for the quarter. Non-innovator products are also subject to an additional rebate. The additional rebate is similar to that discussed above for innovator products, except that the baseline AMP quarter is the fifth full quarter after launch (for non- innovator multiple source drugs launched on April 1, 2013 or later) or the third quarter of 2014 (for those

launched before April 1, 2013). The terms of participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drugs under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain federally funded clinics and safety net hospitals no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid drug rebate program, discussed above. Manufacturers are required to report pricing information to the Health Resources and Services Administration ("HRSA") on a quarterly basis. HRSA has also issued regulations relating to the calculation of the ceiling price as well as imposition of civil monetary penalties for each instance of knowingly and intentionally overcharging a 340B covered entity.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs, such as injectable products, that are administered "incident to" a physician service and are not generally self-administered. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. As with the Medicaid drug rebate program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Medicare Part D beneficiaries once had a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare did not cover their prescription drug costs, known as the coverage gap. However, beginning in 2019, Medicare Part D beneficiaries pay 25% of brand drug costs after they reach the initial coverage limit—the same percentage they were responsible for before they reached that limit—thereby closing the coverage gap. Most of the cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of a drug approved under an NDA is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare beneficiaries in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D.

Federal Contracting/Pricing Requirements

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs, available to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration. The law also requires manufacturers to offer deeply discounted FSS contract pricing for purchases of their covered drugs by the Department of Veterans Affairs, the Department of Defense ("DoD"), the Coast Guard, and the Public Health Service (including the Indian Health Service) in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. FSS pricing to those four federal agencies for covered drugs must be no more than the Federal Ceiling Price ("FCP"), which is at least 24% below the Non-Federal Average Manufacturer Price ("Non-FAMP") for the prior year.

The Non-FAMP is the average price for covered drugs sold to wholesalers or other middlemen, net of any price reductions.

The accuracy of a manufacturer's reported Non-FAMPs, FCPs, or FSS contract prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for civil monetary penalties of $100,000 per incorrect item.

Finally, manufacturers are required to disclose in FSS contract proposals all commercial pricing that is equal to or less than the proposed FSS pricing, and subsequent to award of an FSS contract, manufacturers are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose

commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

Tricare Retail Pharmacy Network Program

The DoD provides pharmacy benefits to current and retired military service members and their families through the Tricare healthcare program. When a Tricare beneficiary obtains a prescription drug through a retail pharmacy, the DoD reimburses the pharmacy at the retail price for the drug rather than procuring it from the manufacturer at the discounted FCP discussed above. In order for the DoD to realize discounted prices for covered drugs (generally drugs approved under NDAs), federal law requires manufacturers to pay refunds on utilization of their covered drugs sold to Tricare beneficiaries through retail pharmacies in DoD's Tricare network. These refunds are generally the difference between the Non-FAMP and the FCP and are due on a quarterly basis. Absent an agreement from the manufacturer to provide such refunds, DoD will designate the manufacturer's products as Tier 3 (non-formulary) and require that beneficiaries obtain prior authorization in order for the products to be dispensed at a Tricare retail network pharmacy. However, refunds are due whether or not the manufacturer has entered into such an agreement.

Branded Pharmaceutical Fee

A branded pharmaceutical fee is imposed on manufacturers and importers of branded prescription drugs, generally drugs approved under NDAs. In each year between 2011 and 2018, the aggregate fee for all such manufacturers ranged from $2.5 billion to $4.1 billion, and has remained at $2.8 billion in 2019 and subsequent years. This annual fee is apportioned among the participating companies based on each company's sales of qualifying products to or utilization by certain U.S. government programs during the preceding calendar year. The fee is not deductible for U.S. federal income tax purposes. Utilization of generic drugs, generally drugs approved under ANDAs, is not included in a manufacturer's sales used to calculate its portion of the fee.

Human Capital Management

We are dedicated to making a meaningful impact on the lives of those suffering from pediatric cancer, and we believe in putting patients first in everything we do. To facilitate talent attraction and retention, we strive to make Fennec an inclusive, safe, and healthy workplace, with opportunities to grow and develop in their careers, supported by strong compensation, benefits, health and welfare programs. Our goal in selecting employees is to retain high quality personnel with substantial prior experience who understand and support our mission as a company to develop and commercialize innovative therapies for people with rare, debilitating, chronic neuromuscular and neurological diseases and who are willing to work hard and in a collaborative manner to further that mission.

Employee Profile

As of December 31, 2022, we had approximately 36 employees, 25 of whom are in our commercial organization, two of whom are in our R&D organization, and the rest of whom are in our G&A organization. We also utilize the services of several full-time consultants who work with our commercial organization. None of our employees are covered by a collective bargaining agreement. We believe our relationship with our employees and consultants is good.

Compensation and Benefits

Our compensation philosophy is to provide pay and benefits that are competitive in the biotechnology and pharmaceutical industry where we compete for talent. We monitor our compensation programs closely and review them at least annually to provide what we consider to be a very competitive mix of compensation and health, welfare and retirement benefits for all our employees. Our compensation package for all employees includes market-competitive base salaries, annual performance bonuses and stock option grants. Our benefits programs include company sponsored medical, dental and vision health care coverage, life and AD&D insurance, and a 401(k) plan among others benefits.

Research and Development

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

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

Research and development expenses totaled $3.5 million and $5.0 million for the fiscal years ended December 31, 2022 and 2021, respectively. We have decreased our research and development expenses related to PEDMARK® as our efforts have shifted to commercial readiness and launch activities.

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

Company Information

We incorporated under the Canada Business Corporations Act ("CBCA”) in September 1996. In August 2011, we continued from the CBCA to the Business Corporations Act (British Columbia) (the “Continuance”). We have four wholly-owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian company, and Fennec Pharmaceuticals (EU) Limited (“Fennec Limited”), an Ireland company. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

Our corporate website is www.fennecpharma.com. We make our periodic and current reports, together with amendments to these reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (“Exchange Act”), available on our website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (“SEC”). Members of the public may also read and copy any materials we file with, or furnish to, the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. To obtain information on the operation of the Public Reference Room, please call the SEC at 1-800-SEC-0330. The SEC maintains a website at www.sec.gov that contains the reports, proxy statements and other information that we file or furnish electronically with the SEC. The Canadian securities regulatory authorities maintain a website at www.sedar.com that contains our filings with the Canadian securities regulatory authorities. Our website and the information contained therein or connected thereto is not intended to be incorporated into this Annual Report or any other report or information we file with the SEC or Canadian securities regulatory authorities.

Item 1A. Risk Factors

An investment in our common shares involves a significant risk of loss. You should carefully read this entire Annual Report and should give particular attention to the following risk factors. You should recognize that other significant risks may arise in the future, which we cannot reasonably foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than currently expected. There are a number of important factors that could cause our actual results to differ materially from those expressed or implied by any of our forward-looking statements in this Annual Report. These factors include, without limitation, the risk factors listed below, and other factors presented throughout this Annual Report and any other documents filed by us with the SEC and the Canadian securities regulators on SEDAR.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results. A more thorough discussion of these and other risks follows this summary.

Risks Related to Our Business

- We have a history of significant losses and have generated limited revenue from the sale of products since our inception.
- We may be required to conduct additional clinical trials for PEDMARK®, which would be costly and time-consuming to complete.
- We may require additional financing to obtain regulatory approval for and commercialize PEDMARK®, and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate further product development, other operations, or commercialization efforts.
- We are currently and may in the future be the target of securities litigation, which may be costly and time-consuming to defend.
- We have only recently transitioned from a development stage biopharmaceutical company to a commercial stage biopharmaceutical company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Our business may be adversely affected by the ongoing COVID-19 pandemic.
- Our business involves environmental risks and potential exposure to environmental liabilities.

Risks Related to Marketing Approval of Our Product Candidate

- PEDMARK® has received marketing approval from the FDA, but not from any comparable foreign authorities. These approval processes are costly, time-consuming, and inherently unpredictable, and it is possible that our applications for marketing approval will be denied.

Risks Related to Commercialization of Our Product Candidate

- Our success depends on our ability to successfully commercialize PEDMARK®. We are a single product company with only limited commercial experience, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.
- If we are unable to successfully commercialize PEDMARK®, our business, results of operations and financial condition may be materially adversely affected.
- Our business is subject to substantial competition.
- Our business may require additional capital.
- The obligations incident to being a public company place significant demands on our management.
- We are highly dependent on our small number of key personnel and advisors.
- The ongoing COVID-19 pandemic and the worldwide attempts to contain it could harm our business and results of operations and financial condition and we could be adversely impacted by it.
- We face a risk of product liability claims and may not be able to obtain adequate insurance.
- Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

- Now that we have received regulatory approvals for PEDMARK®, it will still be subject to continued regulatory review and could be subject to labeling and other restrictions.

- Sales of PEDMARK® will depend on reimbursement by payers and these payers are subject to pressures to contain costs. In addition, coverage and reimbursement for PEDMARK® may be limited or unavailable in certain market segments.

- PEDMARK® targets diseases with small patient populations and we may not be effective at identifying patients.

- We may not be able to gain or maintain market acceptance of PEDMARK® among the medical community, patients, or payers.

- If we fail to comply with applicable healthcare laws and regulations, we may be subject to investigations and civil or criminal penalties and could lose any regulatory approvals that we obtain for PEDMARK®.

- Changes in healthcare laws and regulations, as well as changes in healthcare policy, could adversely affect our business.

Risks Related to Third Parties

- We rely on third parties to supply raw materials, to conduct clinical trials, and to manufacture PEDMARK®. If these third parties fail to satisfactorily perform for us, or if they fail to comply with applicable legal and regulatory requirements, it could have a material adverse effect on our business.

Risks Related to Government Regulation

- • The regulatory approval process is lengthy, and we may not be able to obtain all of the regulatory approvals required to manufacture and commercialize PEDMARK® in all areas in which we are licensed to supply it.

- • We may face significant delays in our clinical studies and trials due to an inability to recruit patients for our clinical studies and trials or to retain patients in the clinical studies and trials we may perform.

- • If our third-party suppliers or contract manufacturers do not maintain appropriate standards of manufacturing in accordance with cGMP and other manufacturing regulations, our development and commercialization activities could suffer significant interruptions or delays.

- • PEDMARK® is subject to ongoing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed.

- • Enacted and future legislation or judicial action may increase the difficulty and cost for us to commercialize PEDMARK® or any other drug candidates we may acquire or license and affect the prices we may obtain.

- • If we fail to obtain or subsequently maintain orphan drug exclusivity or regulatory exclusivity for PEDMARK® and any other orphan drug candidates we may acquire or license, our competitors may sell products to treat the same conditions at greatly reduced prices, and our revenues would be significantly adversely affected.

- • Changes to the Orphan Drug Act or successful legal challenges to the FDA's interpretation of the Orphan Drug Act may affect our ability to obtain or subsequently maintain orphan drug exclusivity or may affect the scope orphan drug exclusivity for our product.

- • Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors are subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal

sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

- Risks Related to Our Intellectual Property

- We are dependent on our relationships and license agreements, and we rely upon the patent rights granted to us pursuant to the license agreements.

- Our success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

- If we cannot obtain new patents, maintain our existing patents, and protect our trade secrets and other intellectual property, our business and competitive position may be harmed.

- Patent protection for PEDMARK® may expire before we are able to fully realize its commercial value.

- We are currently and may in the future be the target of patent litigation, which may be costly and time-consuming to defend.

- Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect PEDMARK®.

- If we are found to be infringing third-party patents, we may be forced to pay damages and/or obtain a license. If we cannot obtain a license, we may be prevented from the manufacture and sale of PEDMARK®.

- It is possible that we could lose market exclusivity for PEDMARK® earlier than expected.

Risks Related to Our Industry

- Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

- The biotechnology and pharmaceutical industry, and in particular the field of cancer therapeutics where we are focused, is highly competitive. We face significant competition from other pharmaceutical, biopharmaceutical, and biotechnology companies, many of which have significantly greater financial, technical, and human resources than we do and may be better equipped to develop, manufacture, and market products.

There are also general risk factors relating to us that you should consider that relate to our business and to our common stock.

Risks Related to Our Business

We have a history of significant losses and have had limited revenues to date through the sale of our product. If we do not generate significant revenues, we will not achieve profitability.

To date, we have been engaged primarily in research and development activities. We have incurred significant operating losses every year since our inception in September 1996. We reported a net loss of approximately $23.71 million for the year ended December 31, 2022 and reported a net loss of approximately $17.35 million for the year ended December 31, 2021. At December 31, 2022, we had an accumulated deficit of approximately $203.2 million. We anticipate incurring substantial additional losses due to the need to spend substantial amounts on activities required for commercialization of PEDMARK® in the U.S. and regulatory approval of PEDMARK® outside of the U.S., as well as commercial launch preparation of PEDMARK® outside of the U.S., anticipated research and development activities, and

general and administrative expenses, among other factors. We may never achieve or sustain profitability on an ongoing basis.

PEDMARK® is currently our only product and there is no assurance that we will successfully develop PEDMARK® into a commercially viable product.

Since our formation in September 1996, we have engaged in research and development programs. We have recently begun to generate revenue from product sales in the United States after regulatory approval of PEDMARK® in late 2022. PEDMARK® is currently our only product. There can be no assurance that the research we fund and manage will lead PEDMARK® or any future product candidate to become a commercially viable product. We have completed two-Phase 3 studies for PEDMARK®. We anticipate substantial regulatory review prior to the commercialization of PEDMARK® outside of the United States.

We may require additional financing to obtain marketing approval of PEDMARK® and commercialize PEDMARK® abroad and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts outside of the United States.

Based on available resources, we believe that our cash and cash equivalents of $23.8 million available as of December 31, 2022 are sufficient to fund our anticipated operating and capital requirements for at least the next 12 months. Moreover, we expect to continue to incur losses for the foreseeable future as we continue our development of and seek marketing approvals for PEDMARK® outside of the United States. We may not be able to obtain additional financing in sufficient amounts or on acceptable terms when needed. If we fail to arrange for sufficient capital on a timely basis, we may be required to curtail our business activities until we can obtain adequate financing. Debt financing must be repaid regardless of whether or not we generate profits or cash flows from our business activities. Equity financing may result in dilution to existing shareholders and may involve securities that have rights, preferences, or privileges that are senior to our common shares or other securities. If we cannot raise sufficient capital when necessary, we will likely have to curtail operations and you may lose part or all of your investment.

Our success depends on our ability to successfully commercialize PEDMARK®. We are a single product company with only limited commercial experience, which makes it difficult to evaluate our current business, predict our future prospects, and forecast our financial performance and growth.

We have invested a significant portion of our efforts and financial resources to date into the development and commercialization of our only product, PEDMARK®. Our success depends on our ability to effectively commercialize PEDMARK®, and we expect that all of our product revenues in the foreseeable future will be from sales of PEDMARK®. Continued commercialization of PEDMARK® is subject to many risks. Until we launched PEDMARK®, we had never launched or commercialized a product, and there is no guarantee that we will be able to achieve profitability and cash flow positive based on our sales of PEDMARK®. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market growth potential, including by pharmaceutical companies with more resources and experience than we have. The long term commercial success of PEDMARK® depends on the extent to which patients and physicians accept and adopt PEDMARK® For example, if the expected patient population is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take PEDMARK®, or if patients discontinue from use of the medication at rates that are higher than we expect, or if payers decide not to reimburse for our product, the commercial potential of PEDMARK® will be limited. Thus, significant uncertainty remains regarding the ultimate commercial potential of PEDMARK®.

Moreover, our ability to effectively generate significant product revenue from PEDMARK® will depend on our ability to, among other things:

- educate patients and physicians successfully about efficacy expectations, side effects expectations, and how to successfully dose and titrate the medication to optimal patient benefit in order to minimize discontinuation due to perceived lack of efficacy or side effects;

- educate pediatric cancer patients who will have cisplatin administration, and the physicians who treat them, as to the benefits to such patients of treatment using PEDMARK® (in addition to the treatments they are receiving for their cancer);

- achieve and maintain compliance with regulatory requirements, including those related to our required post-approval studies, promotion and advertising requirements;

- increase awareness for and achieve market acceptance of PEDMARK® through our sales and marketing activities and other arrangements established for the promotion of PEDMARK®;

- train, deploy, support, and retain a qualified field sales and marketing force;

- secure continued formulary approvals for PEDMARK® with a substantial number of targeted payors;

- ensure that our third-party manufacturers manufacture PEDMARK® in sufficient quantities, in compliance with requirements of the FDA and at acceptable quality and pricing levels, in order to meet commercial demand;

- ensure that our third-party manufacturers develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP regulations;

- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;

- ensure that our entire supply chain efficiently and consistently delivers **PEDMARK®** to our customers;

- provide co-pay assistance to help qualified patients with out-of-pocket costs associated with their **PEDMARK®** prescription, and/or other programs to ensure patient access to our product, educate physicians and patients about the benefits, administration and use of **PEDMARK®**, and obtain acceptance of **PEDMARK®** as safe and effective by patients and the medical community;

- receive adequate levels of coverage and reimbursement for **PEDMARK®** from commercial health plans and governmental health programs;

- generate positive experience with our FennecHears program in helping patients obtain access to **PEDMARK®** at an acceptable patient out-of-pocket cost;

- maintain quality relationships with patient advocacy groups;

- influence the nature of publicity related to our product relative to the publicity related to our competitors' products; and

- obtain regulatory approvals for additional indications for the use of **PEDMARK®** in treating other patient populations.

Any disruption in our ability to generate product revenue from the sale of **PEDMARK®** will have a material and adverse impact on our results of operations.

If we are unable to continue to successfully commercialize PEDMARK®, our business, results of operations and financial condition may be materially adversely affected.

Our strategy is to successfully commercialize PEDMARK® in the United States and abroad. There are risks involved both with maintaining our own sales and marketing capabilities, and with entering into arrangements with third parties to perform these services. For example, any efforts to maintain a direct sales and marketing organization are subject to numerous risks, including:

- the expense and time required to recruit, retain, and motivate members of the sales force;

- our inability to recruit, retain or motivate adequate numbers of effective marketing personnel and partner marketing agencies;
- the inability to provide adequate training to sales and marketing personnel;
- the expense and time required to monitor regulatory compliance;
- the inability of sales personnel to obtain access to physicians or convince adequate numbers of physicians to prescribe any product; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Similarly, as we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability associated with any product revenue may be lower than if we were to market and sell any product that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product effectively. Moreover, we may be negatively impacted by other factors outside of our control relating to such third parties, including, but not limited to, their inability to comply with regulatory requirements. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product.

Finally, because we are using a very small group of exclusive specialty pharmacies to distribute our product, if the organizations that we work with to deliver our drug do not perform in a lawful manner or have issues unrelated to our business, our business could be adversely affected.

Our business is subject to substantial competition.

The biotechnology and pharmaceutical industries are highly competitive. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approvals of products and manufacturing and marketing products than we have. We compete against pharmaceutical companies that are developing or currently marketing therapies that will compete with us. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of drug products. Our business could be negatively impacted if our competitors' present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payors. Further, we may also compete with respect to manufacturing efficiency and marketing capabilities.

For all of these reasons, we may not be able to compete successfully.

If we do not maintain current or enter into new collaborations with other companies, we might not successfully develop our product or generate sufficient revenues to expand our business.

We currently rely on scientific and research and development collaboration arrangements with academic institutions and other third-party collaborators, including an exclusive worldwide license from OHSU for PEDMARK®. We also rely on collaborators for testing PEDMARK®, including SIOPEL and the Children's Oncology Group.

The agreements with OHSU are terminable by either party in the event of an uncured breach by the other party. We may also terminate our agreement with OHSU at any time upon prior written notice of specified durations to OHSU. Termination of any of our collaborative arrangements could materially adversely affect our business. For example, if we are unable to make the necessary payments under these agreements, the licensor might terminate the agreement which might have a material adverse impact. In addition, our collaborators might not perform as agreed in the future.

Since we conduct a significant portion of our research and development through collaborations, our success may depend significantly on the performance of such collaborators, as well as any future collaborators. Collaborators might not commit

sufficient resources to the research and development or commercialization of our product candidate. Economic or technological advantages of products being developed by others, among other factors, could lead our collaborators to pursue other products or technologies in preference to those being developed in collaboration with us. There is a risk of dispute with respect to ownership of technology developed under any collaboration. Our management of any collaboration will require significant time and effort as well as an effective allocation of resources. We may not be able to simultaneously manage a large number of collaborations. Any of these negative impacts on our current or future collaborations could have a material adverse effect on our business and results of operations.

Regulatory approval of our product is time-consuming, expensive and uncertain, and could result in unexpectedly high expenses and delay our ability to sell our product outside of the United States.

Development, manufacture and marketing of our product is subject to extensive regulation by governmental authorities in the United States and other countries. This regulation could require us to incur significant unexpected expenses or delay or limit our ability to sell our product abroad. Our clinical studies might be delayed or halted, or additional studies might be required, for various reasons, including:

- there is a lack of sufficient funding;
- the drug is not effective;
- patients experience severe side effects during treatment;
- appropriate patients do not enroll in the studies at the rate expected;
- drug supplies are not sufficient to treat the patients in the studies; or
- we decide to modify the drug during testing.

If regulatory approval of our product is granted outside of the United States, it will be limited to those indications for which the product has been shown to be safe and effective, as demonstrated to the satisfaction of the FDA and foreign regulators through clinical studies. Furthermore, approval abroad might entail ongoing requirements for post-marketing studies. Even if regulatory approval is obtained outside for the United States, labeling and promotional activities are subject to continual scrutiny by the FDA and state and foreign regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's interpretation of them might impair our ability to effectively market our product.

We and our third-party manufacturers are also required to comply with the applicable cGMP regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities, which we outsource to third parties, must be approved by the FDA before they can be used to manufacture our product, and they are subject to additional FDA inspection. The CRL that we received from the FDA in August, 2020 and in November, 2021 as a result of deficiencies in the third-party manufacturing facility that manufactures PEDMARK® on our behalf is a specific example of the risks associated with our third-party manufacturers.

If we fail to comply with any of the FDA's continuing regulations, or any other regulations under which we may be required to comply outside of the United States, we could be subject to reputational harm and sanctions, including:

- delays, warning letters and fines;
- product recalls or seizures and injunctions on sales;
- refusal of the FDA, or other regulators, to review pending applications;
- total or partial suspension of production;

- withdrawals of previously approved marketing applications; and
- civil penalties and criminal prosecutions.

In addition, identification of side effects after a drug is on the market or the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional testing or changes in labeling of the product.

If our licenses to proprietary technology owned by others are terminated or expire, we may suffer increased development costs and delays, and we may not be able to successfully commercialize our product.

The development of our drug and the manufacture and sale of any products that we develop will involve the use of processes, products and information, some of the rights to which are owned by others. PEDMARK® is licensed under agreements with OHSU. Although we have obtained licenses or rights with regard to the use of certain processes, products and information, the licenses or rights could be terminated or expire during critical periods and we may not be able to obtain, on favorable terms or at all, licenses or other rights that may be required. Some of these licenses provide for limited periods of exclusivity that may be extended only with the consent of the licensor, which may not be granted.

If we are unable to adequately protect or maintain our patents and licenses related to our product, or if we infringe upon the intellectual property rights of others, we may not be able to successfully maintain commercial status of our product.

The value of our product will depend in part upon our ability, and those of our collaborators, to obtain patent protection or licenses to patents, maintain trade secret protection and operate without infringing on the rights of third parties. Although we have successfully pursued patent applications in the past, it is possible that:

- some or all of our pending patent applications, or those we have licensed, may not be allowed;
- proprietary products or processes that we develop in the future may not be patentable;
- any issued patents that we own or license may not provide us with any competitive advantages or may be successfully challenged by third parties; or
- the patents of others may have an adverse effect on our ability to do business.

It is not possible for us to be certain that we are the original and first creator of inventions encompassed by our pending patent applications or that we were the first to file patent applications for any such inventions. Further, any of our patents, once issued, may be declared by a court to be invalid or unenforceable.

PEDMARK® is currently protected by methods of use patent that we exclusively licensed from OHSU that expires in the United States in 2038 and two patents owned by us that expires in 2039. Further, patents are currently pending in the United States and other territories. In addition, periods of marketing exclusivity for PEDMARK® may also be possible in the United States under orphan drug status and in Europe under PUMA.

We may be required to obtain licenses under patents or other proprietary rights of third parties, but the extent to which we may wish or need to do so is unknown. Any such licenses may not be available on terms acceptable to us or at all. If such licenses are obtained, it is likely they would be royalty bearing, which would reduce our future income, if any. If licenses cannot be obtained on an economical basis, we could suffer delays in market introduction of planned products or their introduction could be prevented, in some cases after the expenditure of substantial funds. If we do not obtain such licenses, we would have to attempt to design around patents of third parties, potentially causing increased costs and delays in product development and introduction or precluding us from developing, manufacturing or selling our planned products, or our ability to develop, manufacture or sell products requiring such licenses could be foreclosed.

Litigation may also be necessary to enforce or defend patents issued or licensed to us or our collaborators or to determine the scope and validity of a third party's proprietary rights. By example we have outstanding lititagation against CIPLA.

We could incur substantial costs if litigation is required to defend ourselves in patent suits brought by third parties, if we participate in patent suits brought against or initiated by our collaborators, or if we initiate such suits. We might not prevail in any such action. An adverse outcome in litigation or an interference to determine priority or other proceeding in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties or require us or our collaborators to cease using certain technology or products. Any of these events would likely have a material adverse effect on our business, financial condition and results of operations.

Much of our technological know-how that is not patentable may constitute trade secrets. Our confidentiality agreements might not provide for meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information. In addition, others may independently develop or obtain similar technology and may be able to market competing products and obtain regulatory approval through a showing of equivalency to our product that has obtained regulatory approvals, without being required to undertake the same lengthy and expensive clinical studies that we would have already completed.

The vulnerability to off-label use or sale of our product that are covered only by "method of use" patents may cause downward pricing pressure on the product and may make it more difficult for us to enter into collaboration or partnering arrangements for the marketing of this product in the United States and abroad.

PEDMARK® is currently covered by "method of use" patent and "composition of matter" patent. "Method of use" patents cover the use of certain compounds to treat specific conditions and "composition of matter" patents cover the chemical composition of the compound. Method of use patents provide less protection than composition of matter patents because of the possibility of off-label competition if other companies develop or market the compound for other uses. If another company markets a drug that we expect to market under the protection of a method of use patent, physicians may prescribe the other company's drug for use in the indication for which we obtain approval and have a patent, even if the other company's drug is not approved for such an indication. Off-label use and sales could limit our sales and exert pricing pressure on any product we develop covered only by method of use patents. Also, it may be more difficult to find a collaborator to license or support the marketing of our product that is only covered by method of use patents.

If our third-party manufacturers breach or terminate their agreements with us, or if we are unable to secure arrangements with third party manufacturers on acceptable terms as needed in the future, we may suffer significant production delays and additional costs.

We have little experience manufacturing products and do not currently have the resources to manufacture any products that we may develop. We currently have agreements with contract manufacturers for clinical supplies of PEDMARK®, including drug substance providers and drug product suppliers, but they might not perform as agreed in the future or may terminate our agreements with them before the end of the required term. Significant additional time and expense would be required to effect a transition to a new contract manufacturer.

We plan to continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, preclinical trials, human clinical trials and product commercialization, and to perform their obligations in a timely manner and in accordance with applicable government regulations. If we develop any product with commercial potential, we will need to develop the facilities to independently manufacture such product or products or secure arrangements with third parties to manufacture them. We may not be able to independently develop manufacturing capabilities or obtain favorable terms for the manufacture of our product. While we intend to contract for the commercial manufacture of our product, we may not be able to identify and qualify contractors or obtain favorable contracting terms. We or our contract manufacturers may also fail to meet required manufacturing standards, which could result in delays or failures in product delivery, increased costs, injury or death to patients, product recalls or withdrawals and other problems that could significantly hurt our business. The CRLs that we received from the FDA in August 2020 and November 2021 as a result of deficiencies in the third-party manufacturing facility that manufactures PEDMARK® on our behalf is a specific example of the risks associated with our third-party manufacturers. We intend to maintain a second source for back-up commercial manufacturing, wherever feasible. However, if a replacement to our future internal or contract manufacturers were required, the ability to establish second-sourcing or find a replacement manufacturer may be difficult due to the lead times generally required to manufacture drugs and the need for FDA compliance inspections and approvals of any replacement manufacturer, all of which factors could result in production delays and additional commercialization costs. Such lead times would vary based on the situation but might be twelve months or longer.

We conduct our business internationally and are subject to laws and regulations of several countries which may affect our ability to access regulatory agencies and may affect the enforceability and value of our licenses.

We have conducted clinical trials in the United States, Canada, Europe and the Pacific Rim and intend to, or may, conduct future clinical trials in these and other jurisdictions. There can be no assurance that any sovereign government will not establish laws or regulations that will be deleterious to our interests. There is no assurance that we, as a British Columbia corporation, will continue to have access to the regulatory agencies in any jurisdiction where we might want to conduct clinical trials or obtain regulatory approval, and we might not be able to enforce our licenses or patent rights in foreign jurisdictions. Foreign exchange controls may have a material adverse effect on our business and financial condition, since such controls may limit our ability to flow funds into or out of a particular country to meet obligations under licenses, clinical trial agreements or other collaborations.

Our cash invested in money market funds might be subject to loss.

Even though we believe we take a conservative approach to investing our funds, the nature of financial markets exposes us to investment risk, including the risks that the value and liquidity of our money market investments (the amounts of which substantially exceed the $250,000 amount insured by the FDIC) could deteriorate significantly and the issuers of the investments we hold could be subject to credit rating downgrades. While we have not experienced any loss or write down of our money market investments in the past, we cannot guarantee that such losses will not occur in future periods.

With the clinical development process successfully completed in the United States, our ability to derive further revenues from the sale of PEDMARK® will depend upon our obtaining foreign regulatory approvals, which are subject to a number of unique risks and uncertainties.

Even if we are able to demonstrate the safety and efficacy of our product in clinical trials abroad, if we fail to gain timely approval to commercialize PEDMARK® from foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. Regulatory authorities in other countries may delay, limit or deny approval of PEDMARK® for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials; or with our interpretation of data from our preclinical studies or clinical trials; or may otherwise take the position that PEDMARK® fails to meet the requirements and standards for regulatory approval. During the course of review, foreign regulatory bodies may request or require additional preclinical, clinical, chemistry, manufacturing, and control ("CMC"), or other data and information, and the development and provision of these data and information may be time consuming and expensive. Regulatory approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval.

Further, while we may develop a product with the intention of addressing a large, unmet medical need, the foreign regulatory bodies may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations.

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

Following periods of market volatility in the price of a company's securities or the reporting of unfavorable news, security purchasers have often instituted class action litigation. This risk is especially relevant for us because pharmaceutical companies like us have experienced significant stock price volatility in recent years. Specifically, we were named in putative securities class action complaints as a result of the decline in our stock price following the August 10, 2020 announcement that we had received a CRL from the FDA regarding our NDA for PEDMARK® and as result of the decline in our stock price following the November 29, 2021 announcement that we expected to receive another CRL from the FDA regarding our NDA for PEDMARK®. Regardless of the outcome of this or future litigation, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer. Our insurance coverage may be insufficient to cover all legal fees, judgments or settlements. If the outcome of any

such litigation is unfavorable, it could result in us paying significant damages or settlement payments, which could have a material adverse effect on our financial condition.

We have only recently transitioned from a development stage biopharmaceutical company to a commercial stage biopharmaceutical company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Other than the FDA approval for PEDMARK® received in the United States in September 2022, we have no other product candidates in the development stage. We have only recently demonstrated our ability, or our ability to arrange for a third party, to manufacture a commercial scale medicine and conduct the sales and marketing activities necessary to commercialize a product. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had more experience commercializing PEDMARK®. In addition, as a relatively new commercial stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To be profitable, we will need to continue to successfully transition from a company with a research and development focus to a company capable of supporting commercial activities. Ultimately, we may not be successful in such a transition.

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

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

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

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

Our business and operations could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.

The COVID-19 pandemic is affecting the operations of government entities, such as the FDA, as well as contract research organizations, third-party manufacturers, and other third-parties upon whom we rely. The extent of the impact on our operations depends in part on the time these restrictions remain in place, and whether restrictions are reinstated as a result of a rising surge in COVID-19 cases. These and similar disruptions in our operations could negatively impact our business,

operating results and financial condition. Possible effects may include, but are not limited to, disruption to our product launch outside the United States, which includes the ability of sales reps to communicate with oncologists, absenteeism in our labor workforce, unavailability of products and supplies used in operations, and a decline in value of our assets, including inventories, property and equipment, and marketable securities.

The spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to capital and increases economic uncertainty. To the extent the COVID-19 pandemic adversely affects our business, financial results and value of our common shares, it may also affect our ability to access capital and obtain financing, which could in the future negatively affect our liquidity and ability to continue as a going concern.

The global pandemic of COVID-19 continues to evolve rapidly, and the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full impact of potential delays or effects on our business, our clinical trials, our ability to access the capital markets, or supply chains or on the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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

A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the COVID-19 pandemic), trade wars, political unrest or other events, could disrupt our business or operations or those of our manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. These limitations could negatively affect our business operations and continuity, and could negatively impact our development timelines and ability to timely perform basic business functions, including, without limitation, making SEC filings and preparing financial reports. If our operations or those of third parties with whom we conduct business are impaired or curtailed as a result of these events, the development and commercialization of our product and product candidate could be impaired or halted, which could have a material adverse impact on our business.

Because the target patient population for PEDMARK® is small, we must achieve significant market share and obtain relatively high per-patient prices for our product to achieve meaningful gross margins.

PEDMARK® targets a small patient population. A key component of the successful commercialization of a drug product for these indications includes identification of patients and a targeted prescriber base for the drug product. Due to small patient populations, we believe that we would need to have significant market penetration to achieve meaningful revenues and identifying patients and targeting the prescriber base are key to achieving significant market penetration. Typically, drugs for conditions with small prevalence have higher prices in order to generate a return on investment, and as a result, the per-patient prices at which we sell PEDMARK® are relatively high in order for us to generate an appropriate return for the investment in these product development programs and achieve meaningful gross margins, and high per patient prices could drive physicians to seek out compounding pharmacies to provide compounded sodium thiosulfate to fill their prescriptions rather than PEDMARK®, thereby lowering the PEDMARK® market share or penetration in the market. There can be no assurance that we will be successful in achieving a sufficient degree of market penetration and/or obtaining or maintaining high per-patient prices for PEDMARK® for a small patient populations. Further, even if we obtain significant market share for PEDMARK® because the potential target populations are very small, we may not be able to obtain profitability despite obtaining such significant market share.

We face a risk of product liability claims and may not be able to obtain adequate insurance.

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and/or sale of our drug products. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of drug products used in clinical trials or after FDA approval.Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance that we believe to be adequate. Our insurance may not reimburse us for certain claims or the coverage

may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our current drug candidates, or any potential future products we may acquire and use in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our product, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. Global health concerns, such as the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as the COVID-19 pandemic could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

Risks Related to the Clinical Development and Marketing Approval of Our Product outside the United States

The marketing approval processes of foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product abroad, our business will be substantially harmed.

Our current product has gained marketing approval for sale in the United States but no other country, and we cannot guarantee that we will ever have regulatory approval outside the United States. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidate in abroad a timely manner. We cannot commercialize our product candidate outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Our product could fail to receive marketing approval for many reasons, including the following:

- FDA comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- FDA comparable foreign regulatory authorities may find the human subject protections for our clinical trials inadequate and place a clinical hold on an IND at the time of its submission precluding commencement of any trials or a clinical hold on one or more clinical trials at any time during the conduct of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product's clinical and other benefits outweigh its safety risks;
- FDA comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product may not be sufficient to obtain marketing approval outside of the United States;

- FDA comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies (for example, see the discussion elsewhere concerning the CRLs we received from the FDA in August, 2020 and November 2021); and

- the approval policies or regulations of the FDA comparable foreign regulatory authorities may significantly change in a manner that would delay marketing approval.

Before obtaining marketing approval for the commercial sale of any drug product for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials and, with respect to approval outside the United States, to the satisfaction of the foreign regulatory authorities, that the product is safe and effective for its intended use and that the manufacturing facilities, processes, and controls are adequate to preserve the drug's identity, strength, quality and purity. In September 2022, we obtained approval of our NDA from the FDA. An NDA must include extensive preclinical and clinical data and supporting information to establish the product's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing, and controls for the product. After the submission of an NDA, but before approval of the NDA, the manufacturing facilities used to manufacture a product candidate generally must be inspected by the FDA to ensure compliance with the applicable cGMP requirements (for example, see the discussion elsewhere concerning the CRL we received from the FDA in August, 2020). The FDA and the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities, may also inspect our clinical trial sites and audit clinical study data to ensure that our studies are properly conducted in accordance with the IND regulations, human subject protection regulations, cGCP.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidate. Clinical trials conducted in one country may not be accepted or the results may not be found adequate by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time-consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain marketing approval for, and commercialize product candidates is long, complex and costly, both inside and outside of the United States, and approval is never guaranteed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Even if our product were to successfully obtain approval from regulatory authorities outside the United States, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, warnings or contraindications be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidate. Following any approval for commercial sale of our product candidate, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, may require new studies and will be subject to additional FDA notification, or review and approval. Also, marketing approval for any of our product may be withdrawn. If we are unable to obtain marketing approval for our product in one or more jurisdictions, or any approval contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product will be impaired. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any future product candidates.

Now that we have achieved marketing approval for our product in the United States, it will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Our product could be subject to labeling and other restrictions, and we may be subject to penalties and legal sanctions if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product.

Now that the FDA has approved our product, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP regulations and cGCP for any clinical trials that we conduct post-approval. Any marketing approvals that we receive for our product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, or evidence of acts that raise questions about the integrity of data supporting the product approval, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and foreign regulatory agencies policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval, manufacturing or commercialization of our product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or we are not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Agencies like the FDA and national competition regulators in European countries regulate the promotion and uses of drugs not consistent with approved product labeling requirements. If we are found to have improperly promoted PEDMARK® for uses beyond those that are approved, we may become subject to significant liability.

Regulatory authorities like the FDA and national competition laws in Europe strictly regulate the promotional claims that may be made about prescription products, such as PEDMARK®. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling, known as "off-label" use, nor may it be promoted prior to obtaining marketing approval. If we receive marketing approval for our product candidate for our proposed indications, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label if the physicians personally believe in their professional medical judgment it could be used in such manner. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, the FDA requires that promotional claims not be "false or misleading" as such terms are defined in the FDA's regulations. For example, the FDA requires substantial evidence, which generally consists of two adequate and well-controlled head-to-head clinical trials, for a company to make a claim that its product is superior to another product in terms of safety or effectiveness. Generally, unless we perform clinical trials meeting that standard comparing our product

candidate to competitive products and these claims are approved in our product labeling, we will not be able promote our product as superior to other products. If we are found to have made such claims, we may become subject to significant liability. In the United States, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in improper promotion. The FDA has also requested that companies enter into consent decrees or corporate integrity agreements. The FDA could also seek permanent injunctions under which specified promotional conduct is monitored, changed or curtailed.

Our current and future relationships with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to sanctions.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of our drug post-marketing approval. Our current and future arrangements with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute PEDMARK®. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, and its implementing regulations, which imposed annual reporting requirements for manufacturers of drugs, devices, biologicals and medical supplies for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, where failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties; and

- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our current and future collaborators, if any, are found not to be in compliance with applicable laws, those persons or entities may be subject to criminal, civil or administrative sanctions, including exclusion from participation in government healthcare programs, which could also affect our business.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and healthcare spending on us is currently unknown and may adversely affect our business model.

In the United States and some foreign jurisdictions, legislative and regulatory changes and proposed changes regarding the healthcare system could prevent or delay marketing approval of PEDMARK®, restrict or regulate post-approval activities and affect our ability to profitably sell PEDMARK®.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws and judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, financial condition, results of operations and prospects. There is significant interest in promoting healthcare reform. Among other things, healthcare reform may contain provisions that may reduce the profitability of drug products, including, for example, revising the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, extending the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans, imposing mandatory discounts for certain Medicare Part D beneficiaries, and subjecting drug manufacturers to payment of an annual fee.

We expect that healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The

implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue or commercialize our drugs.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for our product;
- our ability to set a price that we believe is fair for our product;
- our ability to obtain coverage and reimbursement approval for our product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Our employees, sales agents and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, sales agents or consultants. Misconduct could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Commercialization of Our Product

After regulatory approvals in the United States and other territories, the commercial success of our product will depend on market awareness and acceptance of our product.

After obtaining marketing approval for PEDMARK®, it may not gain market acceptance among physicians, key opinion leaders, healthcare payors, patients and the medical community. Market acceptance of PEDMARK® depends on a number of factors, including:

- the timing of market introduction;
- its efficacy and safety, as demonstrated in clinical trials;
- the clinical indications for which it is approved, and the label approved by regulatory authorities for use with the product, including any precautions, warnings or contraindications that may be required on the label;
- acceptance by physicians, key opinion leaders and patients of PEDMARK® as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the number and clinical profile of competing products;
- the growth of drug markets in our various indications;
- relative convenience and ease of administration;
- marketing and distribution support;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

Market acceptance is critical to our ability to generate revenue. PEDMARK®, may be accepted in only limited capacities or not at all. If PEDMARK® is not accepted by the market to the extent that we expect, we may not be able to generate revenue and our business would suffer.

If the market opportunities for our product are smaller than we believe they are, then our revenues may be adversely affected, and our business may suffer.

The market opportunities that our product is being developed to address are rare. Our projections of both the number of people who are administered cisplatin, as well as the subset of people who have the potential to benefit from treatment with our product, and our assumptions relating to pricing are based on estimates. Given the small number of patients that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidate.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product, which could make it difficult for us to sell our product profitably.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved pharmaceuticals. Market acceptance and sales of our product will depend significantly on the availability of coverage and adequate reimbursement from third-party payors and may be affected by existing and future healthcare reform measures. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Government authorities and third-party payors, such as private health insurers, health maintenance organizations, and government payors like Medicare and Medicaid, decide which drugs they will pay for and establish reimbursement levels. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available for PEDMARK® and, even if coverage is provided, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, PEDMARK®.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is, among other things:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and adequate reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to conduct expensive pharmacoeconomic studies and provide supporting scientific, clinical and cost-effectiveness data for the use of our product to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and adequate reimbursement. In addition to examining the medical necessity and cost-effectiveness of new products, coverage may be limited to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. There may also be formulary placements that result in lower reimbursement levels and higher cost-sharing borne by patients, any of which could have an adverse effect on our revenues and profits. Moreover, a third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the drug product, or even if coverage is available, establish an adequate reimbursement rate.

We cannot be sure that coverage or adequate reimbursement will be available for our product. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our product. In the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services and questioning safety and efficacy. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. Additionally, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. If third-party payors do not consider our product to be cost-effective compared to other available therapies, they may not cover our product or, if they do, the level of payment may not be sufficient to allow us to sell our product at a profit.

Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time, and there is the potential for significant movement in these areas in the foreseeable future. Even if favorable coverage and reimbursement status is attained for our product, less favorable coverage policies and reimbursement rates may be implemented in the future.

We face substantial competition, which may result in others discovering, developing or commercializing products more successfully, than we do.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are generally developing and marketing therapeutic products. Such competition may include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic companies and medical technology companies. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product for the treatment of orphan and ultra-orphan diseases for which there is a small patient population in both the United States and in all other potential markets. A drug designated an orphan drug may receive up to seven years of exclusive marketing in the United States for that indication.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, development, technical and human resources than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing clinical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established companies may also invest heavily to accelerate discovery and development of compounds that could make our product obsolete. As a result of all of these factors, maintaining orphan drug designation for our product candidate is essential to our viability since our competitors may, among other things:

- have greater name and brand recognition, financial, manufacturing, marketing, development, technical and human resources;
- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain quicker marketing approval;
- establish superior proprietary positions;
- have access to more manufacturing capacity as well as to more cost-effective manufacturing capacity;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these events occur, our business, financial condition, results of operations, and prospects could be materially adversely affected. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

We believe that our ability to successfully compete will depend on our ability to maintain orphan drug designation as well as:

- achieving and maintaining compliance with regulatory requirements applicable to our business;
- the timing and scope of regulatory approvals, including labeling;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare and Medicaid;
- our ability to protect intellectual property rights related to our product;
- our ability to commercialize and market our product;
- our ability to manufacture and sell commercial quantities of our product;
- acceptance of our product by physicians, other healthcare providers and patients; and
- the cost of treatment in relation to alternative therapies.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Rapid technological change could make our product obsolete.

Pharmaceutical technologies have undergone rapid and significant change, and we expect that they will continue to do so. As a result, there is significant risk that our product may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product is rendered obsolete by advancements in pharmaceutical technologies, our prospects will suffer.

We face a risk of product liability claims and may not be able to obtain adequate insurance.

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and/or sale of our pharmaceutical product. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance that we believe to be adequate. However, our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our drug and, therefore, the amount of insurance coverage we currently hold

may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our product, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

Risks Related to Government Regulation

PEDMARK® is subject to ongoing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed.

We are and will continue to be subject to continuing regulatory review for our product, including the review of our required nonclinical and clinical post-marketing studies, and other clinical results which are reported after our drug becomes commercially available. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during preapproval clinical studies and trials. In addition, both we and the manufacturing facilities we use to make our product will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with us, the manufacturing facilities or our product may result in restrictions on us, the manufacturing facilities or our product, including withdrawal of our product from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension, or withdrawal of regulatory approval, product recalls and seizures, operating restrictions, and criminal prosecutions.

Our product promotion and advertising are also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our product will be limited by the terms and conditions of the FDA-approved labeling and available scientific data. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our product for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety related information, the FDA could allege that our promotional activities misbrand our product. Specifically, the FDA could issue an untitled letter or warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling to all recipients of the misbranded materials. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction, or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies and executives that promote drugs or biologics for unapproved uses, based on the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other federal laws governing the marketing and reimbursement for such products under federally supported healthcare programs such as Medicare and Medicaid. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and potential exclusion of a company’s products from federal healthcare programs.

Enacted and future legislation or judicial action may increase the difficulty and cost for us to commercialize PEDMARK®

In the United States, there have been a number of court cases, legislative and regulatory changes, and other potential changes relating to the healthcare system that restrict or regulate post-approval activities, which may affect our ability to profitably sell PEDMARK® or any other drug candidates for which we obtain marketing approval.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for drug products. The legislation expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies whereby they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and reimbursement that we receive for our product and could seriously harm our business. Manufacturers' contributions to this area, including donut hole coverage (as described below) or potential excise taxes, are increasing and are subject to additional changes in the future.

In 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, the "Health Care Reform Law"), a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The Health Care Reform Law, among other things, revised the definition of Average Manufacturer Price used by the Medicaid Drug Rebate Program for reporting purposes, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and established an annual non-deductible fee on entities that sell branded prescription drugs or biologics to specified government programs in the United States. The Health Care Reform Law also expanded the 340B drug discount program (excluding orphan drugs), including the creation of new penalties for non-compliance and included a discount (now 70%, on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole." The Health Care Reform Law increased the Medicaid rebates for line extensions or reformulated drugs, which could substantially increase our Medicaid rebate rate (in effect limiting reimbursement for these patients).

Beginning in January 2017, former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Health Care Reform Law or otherwise circumvent some of the requirements for health insurance mandated by the Health Care Reform Law. These actions include directing applicable federal agencies to waive, defer, grant exemptions from, or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an Executive Order was signed terminating the cost sharing subsidies that reimburse insurers under the Health Care Reform Law. Several state Attorneys Generals filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018 the United States Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12.0 billion in Health Care Reform Law risk corridor payments to third-party payors. The effects of this gap in reimbursement on third-party payors, the viability of the Health Care Reform Law marketplace, providers, and our business, are not yet known. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit ruled that the Health Care Reform Law's individual mandate is unconstitutional but sent the matter back down to a district court to determine whether that provision can be removed from the rest of the Health Care Reform Law. On March 2, 2020, the U.S. Supreme Court agreed to review the Fifth Circuit's ruling, and oral argument was heard on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the challenge to the Health Care Reform Law in a 7-2 decision.

Additionally, in response to controversies regarding pricing of drug products, there has been a recent push to propose legislation, both on state and federal levels, that would require greater disclosure as to the reasoning behind drug prices and, in some cases, could give state or federal-level commissions the right to impose cost controls on certain drugs. These and other new provisions are likely to continue the pressure on pharmaceutical pricing, may require us to modify our business practices with healthcare practitioners, and may also increase our regulatory burdens and operating costs. In that regard, President Biden and members of Congress in both parties have expressed concerns about high drug prices. However, whether and to what extent any such positions will result in changes of the law, and how any such changes could impact our business, cannot be determined at this time.

Legislative and regulatory proposals also have been made to expand post-approval requirements, restrict sales and promotional activities for drug products, and with respect to orphan drug designation and exclusivity. In addition, increased scrutiny by the United States Congress of the FDA's approval process may subject us to more stringent product labeling and post-marketing testing and other requirements. Delays in feedback from the FDA may affect our ability to quickly update or adjust our label in the interest of patient adherence and tolerability. We cannot predict whether other legislative changes will be adopted or how such changes would affect the pharmaceutical industry generally and specifically the commercialization of PEDMARK®.

If we fail to obtain or subsequently maintain orphan drug exclusivity or regulatory exclusivity for PEDMARK®, our competitors may sell products to treat the same conditions at greatly reduced prices, and our revenues would be significantly adversely affected.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. The company that first obtains FDA approval for a designated orphan drug for a given rare disease receives marketing exclusivity for use of that drug for the stated disease or condition for a period of seven years, with an additional six months of exclusivity if the product also qualifies for pediatric exclusivity. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, a subsequent product is deemed clinically superior, or if the manufacturer is unable to deliver sufficient quantity of the drug.

Because the extent and scope of patent protection for some of our drug products may be particularly limited, orphan drug designation – and ultimately, orphan drug exclusivity – is especially important for our product. For eligible drugs, we plan to rely on the orphan exclusivity period to maintain a competitive position. However, if we do not obtain orphan drug exclusivity for our drug candidates or we cannot maintain orphan exclusivity for our drug candidates, our competitors may then sell the same drug to treat the same condition and our revenues will be reduced. Also, without strong patent protection, competitors may sell a generic version upon the expiration of orphan exclusivity if our patent position is not upheld.

Even after an orphan drug is approved, the FDA can subsequently approve a drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. The FDA can discontinue orphan drug exclusivity after it has been granted if the orphan drug cannot be manufactured in sufficient quantities to meet demand.

Finally, there can be no assurance that the exclusivity provisions currently in the law may not be changed in the future and the impact of any such changes (if made) on us. The orphan drug exclusivity contained in the Orphan Drug Act has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. There can be no assurance that the exclusivity granted in the Orphan Drug Act to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our product, if approved.

Changes to the Orphan Drug Act or successful legal challenges to the FDA's interpretation of the Orphan Drug Act may affect our ability to obtain or subsequently maintain orphan drug exclusivity or affect the scope of orphan drug exclusivity for our product.

There can be no assurance whether the exclusivity provisions in the Orphan Drug Act may be changed in the future and the impact of such changes, if made on us.

The orphan drug exclusivity contained in the Orphan Drug Act has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. Furthermore, the FDA's interpretations of the Orphan Drug Act have been successfully challenged in court and future court decisions could continue that trend. There can be no assurance that the exclusivity granted in the Orphan Drug Act to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our product, if approved.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors are subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors, customers, and patients expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our drug. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations include the following:

- the Federal health care program Anti-Kickback Statute, which prohibits individuals and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced care practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product successfully and could harm our reputation and lead to reduced acceptance of our product by the market. These enforcement actions include, not only civil and criminal penalties, but also exclusion from participation in government-funded healthcare programs, and exclusion from eligibility for the award of government contracts for our product.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Risks Related to Third Parties

We rely on third-party suppliers and other third parties for production of our product and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product.

We do not currently own or operate manufacturing facilities for clinical or commercial production of our product. We lack the resources and the capability to manufacture our product on a clinical or commercial scale. Instead, we rely on, and expect to continue to rely on, third parties for the supply of raw materials and manufacture of drug supplies necessary to

conduct our preclinical studies and clinical trials. Our reliance on third parties may expose us to more risk than if we were to manufacture our current product or other products ourselves. Delays in production by third parties could delay our clinical trials or have an adverse impact on any commercial activities. In addition, the fact that we are dependent on third parties for the manufacture of and formulation of our product means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. Although we oversee these activities to ensure compliance with our quality standards, budgets and timelines, we have had and will continue to have less control over the manufacturing of our product than potentially would be the case if we were to manufacture our product. Further, the third parties we deal with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, which would adversely affect the manufacturing and production of our product. In addition, a third party could be acquired by, or enter into an exclusive arrangement with, one of our competitors, which would adversely affect our ability to access the formulations we require.

Problems with the quality of the work of third parties may lead us to seek to terminate our working relationships and use alternative service providers. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture our drug in an acceptable manner and at an acceptable cost and on a timely basis. The sale of products containing any defects or any delays in the supply of necessary services could adversely affect our business, financial condition, results of operations, and prospects.

Growth in the costs and expenses of components or raw materials may also adversely affect our business, financial condition, results of operations, and prospects. Supply sources could be interrupted from time to time and, if interrupted, supplies may not be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

We plan to rely on third parties to conduct clinical trials for our product. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain marketing approval for or commercialize our product outside of the United States.

Clinical trials must meet applicable foreign regulatory requirements. We do not have the ability to independently conduct clinical trials for our product abroad. We expect to rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the other foreign regulatory authorities require us to comply with IND and human subject protection regulations and cGCP standards, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. Regulatory authorities enforce these cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and the foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process abroad.

There are significant requirements imposed on us and on clinical investigators who conduct clinical trials that we sponsor. Although we are responsible for selecting qualified CROs or clinical investigators, providing them with the information they need to conduct the clinical trials properly, ensuring proper monitoring of the clinical trials, and ensuring that the clinical trials are conducted in accordance with the general investigational plan and protocols contained in the IND, we cannot ensure that the CROs or clinical investigators will maintain compliance with all regulatory requirements at all times. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record data, omit data, or even falsify data. We cannot ensure that the CROs or clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition.

We or the third parties we rely on may encounter problems in clinical trials that may cause us or the foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully

complete clinical trials in a timely fashion, if at all. Furthermore, we or foreign regulatory agencies may suspend clinical trials of our product at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation.

The foreign regulatory agencies could also require additional clinical trials before or after granting of marketing approval for our product, which would result in increased costs and significant delays in the development and commercialization of our product and could result in the withdrawal of our product from the market after obtaining marketing approval. Our failure to adequately demonstrate the safety and efficacy of our product in clinical development could delay or prevent obtaining marketing approval of the product and, after obtaining marketing approval, data from post-approval studies could result in our product being withdrawn from the market, either of which would likely have a material adverse effect on our business.

Risks Related to Our Intellectual Property

We are dependent on our relationships and license agreements, and we rely upon the patent rights granted to us pursuant to the license agreements.

Our commercial success will depend in large part on our ability to use patents and regulatory exclusivity to exclude others from competing with our product. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims sufficiently broad to prevent others from practicing our technologies or marketing competing products. Third parties may intentionally attempt to design around our patents or design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others.

As a result of the foregoing factors, we cannot be certain how much protection from competition patent rights will provide us.

Our success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

While we are not currently aware of any third-party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our product that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our product or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we are aware that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

If a third-party claims that we infringe its patents, any of the following may occur:

- we may be required to pay substantial financial damages if a court decides that our technologies infringe a competitor’s patent, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of our product and intellectual property rights;

- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

- we may have to redesign our product so that it does not infringe others' patent rights, which may not be possible or could require substantial funds or time and require additional studies.

In addition, employees, consultants, contractors and others may use the proprietary information of others in their work for us or disclose our proprietary information to others. If our employees, consultants, contractors or others disclose our data to others or use data belonging to others in connection with our business, it could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties.

The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

There is substantial history of litigation and other proceedings regarding patent and intellectual property rights in the pharmaceutical industry. We may be forced to defend claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of intellectual property litigation is subject to substantial uncertainties and may, for example, turn on the interpretation of claim language by the court, which may not be to our advantage, or on the testimony of experts as to technical facts upon which experts may reasonably disagree.

As discussed above under the heading Legal Proceedings "Business – Overview – Product," on October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed two petitions for inter partes review ("IPR") with the Patent Trial and Appeal Board ("PTAB") of the USPTO. In its petitions, Hope seeks to invalidate our U.S. Patent No. 10,596,190 ("US '190"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using PEDMARK®, and our U.S. Patent No. 10,792,363 ("US '363"), which relates to an anhydrous form of STS, which is the active pharmaceutical ingredient in our PEDMARK® product. US '190 was issued on March 24, 2020. US '363 was issued on October 6, 2020. We filed preliminary responses to the petitions in February 2022, and thereafter, the PTAB has three months to decide whether to institute IPR proceedings. If the PTAB institutes one or both reviews, the final written decision(s) will be due about one year after the PTAB's decision to institute IPR proceedings, and following additional submissions by the parties. Any appeals of a PTAB decision would delay any final outcome. We plan to vigorously defend our intellectual property rights related to PEDMARK®. However, we are unable to predict the outcome of these petitions, and an invalidation of one or both of these patents may have a material adverse effect on our ability to protect our rights in PEDMARK® beyond the market exclusivity granted from Orphan Drug Designation and PUMA.

On January 11, 2022, our licensor OHSU filed a Request for Supplemental Examination of US '190 requesting the consideration by the USPTO of certain prior art references, including references cited by Hope in its Petition for IPR that are relevant to the granted claim of the patent. On January 28, 2022, the USPTO found that the cited references constitute a substantial new question of patentability and ordered an ex parte reexamination of the single US '190 claim of pursuant to 35 U.S.C. § 257. We are unable to predict the outcome of the *ex parte* reexamination. If the USPTO does not uphold the '190 claim as granted or in amended form, our ability to protect our PEDMARK® product beyond the market exclusivity granted from Orphan Drug Designation and PUMA may be adversely affected.

Under our license agreements, we have the right to bring legal action against any alleged infringers of the patents we license. However, we are responsible for all costs relating to such potential litigation. We have the right to any proceeds received as a result of such litigation, but, even if we are successful in such litigation, there is no assurance we would be awarded any monetary damages.

Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and may have a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing our product. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings with the USPTO or in other proceedings outside

the United States, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted from product development or other more productive matters.

Our proprietary rights may not adequately protect our technologies and product.

Our commercial success will depend in part on our ability to obtain patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as United States laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and product are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product, as we deem appropriate. However, we may fail to apply for patents on important technologies or product in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. We cannot be certain that our patent applications will be approved or that any patents issued will adequately protect our intellectual property.

While we are responsible for and have control over the filing and prosecuting of patent applications and maintaining patents which cover making, using or selling PEDMARK®, we may lose any such rights if we decide to allow any licensed patent to lapse. If we fail to appropriately prosecute and maintain patent protection for PEDMARK®, our ability to develop and commercialize PEDMARK® may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- any of the patents that cover our product will be eligible to be listed in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any patents issued to us or our licensors and collaborators will provide us with any competitive advantages, or will be challenge by third parties;
- we will develop additional proprietary technologies that are patentable;
- the United States government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or
- our business may infringe the patents or other proprietary rights of others.

The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patents and our financial ability to enforce our patents and other intellectual property. Our ability to maintain and solidify our proprietary position for our product will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products.

We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, we or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors and we may not have adequate remedies in respect of that disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, foreign courts are sometimes less willing than United States courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may seek approval to market their own products similar to or otherwise competitive with our product. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. For example, we have received a Paragraph IV certification notice letter from CIPLA, Inc., or CIPLA, indicating that it has submitted to FDA an abbreviated new drug application, or ANDA, seeking approval to manufacture and sell a generic version PEDMARK® (sodium thiosulfate solution) prior to the expiration of certain Orange Book-listed patents protecting PEDMARK®. In an ANDA, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patent or that such patent is invalid is known as a Paragraph IV certification. The CIPLA ANDA contains Paragraph IV certifications with respect to two of our patents covering PEDMAR, U.S. Patent '190, expiration date May 2038; and '728, expiration date May 2039. We filed a patent infringement lawsuit against CIPLA, and vigorously defend and enforce our intellectual property rights protecting PEDMARK, but we can offer no assurance that our efforts we will be successful in which case our business may be materially and adversely affected.

The patent protection for our product may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our product have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review. For example, depending on the timing, duration and specifics of FDA marketing approval of our product, if any, one of the United States patents covering each of such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product.

Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our United States and foreign patents.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

We may become involved in lawsuits to protect our patents or other intellectual property rights, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, directly or through our licensors, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents or the patents we license at risk of being invalidated or interpreted narrowly and could put our or our licensors' patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or the patents of our licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, potential infringers of our intellectual property rights may have

substantially more resources than we do to defend their position, which could adversely affect the outcome of any such dispute.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Third-party claims of intellectual property infringement or misappropriation may adversely affect our business and could impede our ability to profitably commercialize our product.

Our commercial success depends in part on us not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex-parte review and inter partes reexamination and post-grant review proceedings before the USPTO and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product may be subject to claims of infringement of the patent rights of third parties. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement, which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which the collaborator would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidate that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product could have been filed by others without the knowledge of us or our licensors. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product or the use or manufacture of our product. We may also face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, and we may be required to pay damages.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize our product until such patent expired or unless we obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

Ultimately, we could be prevented from commercializing our product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us develop our product's market fully.

Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents and patent rights. Obtaining and enforcing patents and patent rights in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, several recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents and patent rights, once obtained.

For our United States patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act (the "America Invents Act" or "AIA") was signed into law. The AIA includes a number of significant changes to United States patent law, including provisions that affect the way patent applications will be prosecuted, reviewed after issuance, and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of patent rights, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before a licensor or us could therefore be awarded a patent covering an invention of ours even if said licensor or we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patent rights depends on whether the differences between the licensor's or our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that a licensor or we were the first to either (a) file any patent application related to our product or (b) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all United States patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid as unpatentable even though the same evidence may be insufficient to invalidate the claim if first presented in a district court

action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent rights that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to our product but that are not covered by the claims of the patents that we license from others or may license or own in the future;
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights;
- Any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own or license or will, in the future, own or license;
- Issued patents that have been licensed to us may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have license rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- Ownership of patents or patent applications licensed to us may be challenged by third parties;
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Confidentiality agreements with employees, consultants and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development or commercialization of our product. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers.

Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business.

Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to assist with research and development and to manufacture our product, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Industry

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we, or our potential partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and may continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials.

The outcome of clinical testing is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. In addition, regulations are not static, and regulatory agencies, including the FDA, alter their staff, interpretations and practices and may in the future impose more stringent requirements than are currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfying regulatory requirements typically takes a significant number of years and can vary substantially based on the type, complexity and novelty of the product candidate. Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials. Factors that could impede our ability to generate commercially viable products through the conduct of clinical trials include:

- insufficient funds to conduct clinical trials;
- the inability to find partners, if necessary, for support, including research, development, manufacturing or clinical needs;
- the failure of clinical trials to demonstrate the safety and efficacy of our product to the extent necessary to obtain regulatory approvals;
- the failure by us or third-party investigators, CROs, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- the failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- any delay in completion of clinical trials caused by a regional disturbance where we or our collaborative partners are enrolling patients in clinical studies, such as pandemic, terrorist activities, or war, or political unrest, a natural disaster or any other reason or event, resulting in increased costs;
- any delay in obtaining advice from the FDA or similar regulatory authorities; and
- the inability to obtain regulatory approval of our product candidate following completion of clinical trials, or delays in obtaining such approvals.

There can be no assurance that if our clinical trials are successfully initiated and completed, we will be able to obtain approval by regulatory authorities elsewhere in the world in a timely manner, if at all. For example, as described elsewhere, we received a CRL from the FDA in August, 2020 and November 2021, regarding our NDA for PEDMARK®, stating that it was unable to approve the application in its current form based on deficiencies identified by the FDA after completion of a pre-approval inspection of the manufacturing facility of our third-party drug product manufacturer. Although we are successful in resolving the matters raised by the FDA in the CRL, there is no guarantee we will receive regulatory approval elsewhere in the world for PEDMARK® on a timely basis or at all. If we fail to successfully develop and commercialize PEDMARK® outside of the United States, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

We use hazardous materials and chemicals in our research and development, and our failure to comply with laws related to hazardous materials could materially harm us.

Our research and development processes, while outsourced, does involve the controlled use of hazardous materials, such as flammable organic solvents, corrosive acids and corrosive bases. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. We could be held liable for any damages that result and any such liability could exceed our resources and may not be covered by our general liability insurance. We currently do not carry insurance specifically for hazardous materials claims. We may be required to incur significant costs to comply with environmental laws and regulations, which may change from time to time.

Efforts to reduce product pricing and health care reimbursement and changes to government policies could negatively affect the profitability of our product.

Now that our product has achieved regulatory approval in the United States, we may be materially adversely affected by the continuing efforts of governmental and third-party payers to contain or reduce health care costs. The constraints on pricing and availability of competitive products may further limit our pricing and reimbursement policies as well as adversely impact market acceptance and commercialization of our product.

In many markets, the pricing or profitability of healthcare products is subject to government control. In recent years, federal, state, provincial and local officials and legislators have proposed or are proposing a variety of price-based reforms to the healthcare systems in the United States, Canada and elsewhere. Some proposals include measures that would limit or eliminate payments from third-party payors to the consumer for certain medical procedures and treatments or allow government control of pharmaceutical pricing. The adoption of any such proposals or reforms could adversely affect the commercial viability of our product.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Affordable Care Act was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our product.

Since its enactment, there have been judicial and Congressional challenges to numerous aspects of the Affordable Care Act. There may also be federal and state regulatory changes that impact the Affordable Care Act or healthcare programs, insurance coverage or reimbursement generally. These efforts have increased uncertainty regarding the availability of healthcare programs, insurance coverage and reimbursement as a general matter as well as for our product, and we cannot predict how these events will impact our business.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product or additional pricing pressures.

Any significant changes in the healthcare system in the United States, Canada or abroad would likely have a substantial impact on the manner in which we conduct business and could have a material adverse effect on our ability to raise capital and the viability of product commercialization.

Risks Related to Owning Our Common Shares

We may be unable to maintain the listing of our common shares on the Nasdaq Capital Market or the TSX and that would make it more difficult for shareholders to dispose of our common shares.

Our common shares are currently listed on the Nasdaq Capital Market and the Toronto Stock Exchange (the "TSX"). Both the Nasdaq Capital Market and the TSX have rules for continued listing, including minimum market capitalization and other requirements that we might not meet in the future. While we are exercising diligent efforts to maintain the listing of our common shares on the NASDAQ Capital Market and TSX, there can be no assurance that we will be able to do so, and our securities could be delisted.

Delisting from the Nasdaq Capital Market or the TSX would make it more difficult for shareholders to dispose of our common shares and more difficult to obtain accurate quotations on our common shares. This could have an adverse effect on the price of our common shares. There can be no assurances that a market maker will make a market in our common shares on the OTCBB or any other stock quotation system after delisting. Furthermore, securities quoted over-the-counter generally have significantly less liquidity than securities traded on a national securities exchange, not only in the number of shares that can be bought and sold, but also through delays in the timing of transactions and lower market prices than might otherwise be obtained. As a result, shareholders might find it difficult to resell shares at prices quoted in the market or at all. Furthermore, because of the limited market and generally low volume of trading in our common shares, our common shares are more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market's perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the limited market and low trading volume of our common shares.

The market price of our common shares is highly volatile and could cause the value of your investment to significantly decline.

Historically, the market price of our common shares has been highly volatile and the market for our common shares has from time-to-time experienced significant price and volume fluctuations, some of which are unrelated to our operating performance. From January 1, 2018 to March 27, 2023, the closing trading price of our stock fluctuated from a high of $18.45 Canadian dollars ("CAD") per share to a low of CAD$4.38 per share on the TSX. From September 13, 2017 (the date our common shares were first listed on the Nasdaq Capital Market) to March 27, 2023, the closing trading price of our stock fluctuated from a high of $14.33 per share to a low of $3.30 on the Nasdaq Capital Market. Historically, our common shares have had a low trading volume, and may continue to have a low trading volume in the future. This low volume may contribute to the volatility of the market price of our common shares. It is likely that the market price of our common shares will continue to fluctuate significantly in the future.

The market price of our common shares may be significantly affected by many factors, including without limitation:

- the commercialization of our sole product candidate, PEDMARK®;
- the need to raise additional capital and the terms of any transaction we are able to enter into;
- other external factors generally or stock market trends in the pharmaceutical or biotechnology industries specifically;
- announcements of licensing agreements, joint ventures, collaborations or other strategic alliances that involve our product or those of our competitors;
- innovations related to our or our competitors' products;
- actual or potential clinical trial results related to our or our competitors' products;
- the status, timing and outcome of regulatory approvals;

- our financial results or those of our competitors;
- reports of securities analysts regarding us or our competitors;
- developments or disputes concerning our licensed or owned patents or those of our competitors;
- developments with respect to the efficacy or safety of our product or those of our competitors; and
- health care reforms and reimbursement policy changes nationally and internationally.

Our existing principal shareholders hold a substantial number of our common shares and may be able to exercise influence in matters requiring approval of our shareholders.

At March 29, 2023, our current shareholders separately representing more than 5% ownership of our common shares collectively represented beneficial ownership of approximately 43.51% of our common shares. In particular, Southpoint Capital Advisors LP ("Southpoint Capital") owns or exercises control over approximately 4.0 million shares, representing approximately 15.47% of our issued and outstanding common shares; Essetifin SpA, owns approximately 4.0 million shares, or approximately 15.15% of our issued and outstanding common shares; Sonic Fund II, LP, owns approximately 2.5 million shares, or approximately 9.47% of our issued and outstanding common shares; and Avaro Capital Advisors, owns approximately 1.7 million shares, or approximately 6.34% of our issued and outstanding common shares. Southpoint Capital, Essetifin SpA, Sonic Fund II, LP, Avaro Capital Advisors, and our other significant shareholders, and other insiders, acting alone or together, might be able to influence the outcomes of matters that require the approval of our shareholders, including but not limited to certain equity transactions (such as a financing), an acquisition or merger with another company, a sale of substantially all of our assets, the election and removal of directors, or amendments to our incorporating documents. These shareholders might make decisions that are adverse to your interests. The concentration of ownership could have the effect of delaying, preventing or deterring a change of control of our Company, which could adversely affect the market price of our common shares or deprive our other shareholders of an opportunity to receive a premium for our common shares as part of a sale of our Company.

There are a large number of our common shares underlying outstanding options, and reserved for issuance under our stock option plan, that may be sold in the market, which could depress the market price of our shares and result in substantial dilution to the holders of our common shares.

The sale or issuance of a substantial amount of our common shares in the future could cause the market price of our common shares to decline. It may also impair our ability to obtain additional financing. At March 29, 2023, we had outstanding warrants to purchase approximately 0.2 million shares of our common shares at an exercise price of $7.71 per common share. In addition, at March 29, 2023, there were approximately 4.5 million common shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of $5.43 per common share. We may also issue further warrants as part of any future financings in addition to the additional 2.1 million options to acquire our common shares currently remaining and available for future awards under our stock option plan.

We may need to raise additional funds in the future to continue our operations. Any equity offering could result in significant dilution to the ownership interests of shareholders and may result in dilution of the value of such interests and any debt offering will increase financial risk.

In order to satisfy our anticipated capital requirements to commercialize our product, we may need to raise additional funds through either the sale of additional equity, the issuance of securities convertible into equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out-license or sale of certain aspects of our intellectual property portfolio, or from other sources. The most likely sources of financing that may be available to us in the near term are the sale of common shares and/or securities convertible or exercisable into common shares and the issuance of debt.

We cannot predict the size of future issues of common shares or the future issue of securities convertible or exercisable into common shares or the effect that any such future issues and sales of common shares or other securities will have on the market price of our common shares. Any transaction involving the issue of common shares, or securities convertible or exercisable into common shares, could result in immediate and substantial dilution to present and prospective holders of our common shares. Alternatively, we may rely on debt financing and assume debt obligations that require us to make

substantial interest and capital payments and to pledge some or all of our assets as collateral to secure such debt obligations. Failure to meet out debt obligations could result in an acceleration of the debt and enforcement against our assets pledged as collateral, either of which would have an adverse effect on our operations and prospects.

Our management has significant flexibility in using the current available cash.

In addition to general corporate purposes (including working capital, research and development, business development and operational purposes), we currently intend to use our available cash to commercialize our product in the United States while continuing to seek regulatory approval for, and to invest in precommercial activities for PEDMARK® outside of the United States. Depending on future developments and circumstances, we may use some of our available cash for other purposes, which may have the potential to decrease our cash runway. Notwithstanding our current intentions regarding use of our available cash, our management will have significant flexibility with respect to such use. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount and timing of cash used in our operations and our research and development efforts. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costlier to raise funds in the future.

We have not paid any dividends since incorporation and do not anticipate declaring any dividends in the foreseeable future. As a result, you may not be able to recoup your investment through the payment of dividends on your common shares and the lack of a dividend payable on our common shares might depress the value of your investment.

For the foreseeable future, we plan to use all available funds to finance the commercialization of our product and operate our business. Our directors will determine if and when dividends should be declared and paid in the future based on our financial position at the relevant time, but since we have no present plans to pay dividends, you should not expect receipt of dividends either for your cash needs or to enhance the value of our common shares held by you.

We may be a passive foreign investment company, or "PFIC," which could result in adverse United States federal income tax consequences to U.S. investors.

If we are a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder (as such term is defined in the section of this Annual Report entitled "Material U.S. Federal Income Tax Considerations") of our common shares, the U.S. Holder may be subject to adverse U.S. federal income tax consequences and may be subject to additional reporting requirements. We have not made the analysis necessary to determine whether or not we are currently a PFIC or whether we have ever been a PFIC, and there can be no assurances with respect to our status as a PFIC for our current taxable year or any subsequent taxable year. If we are a PFIC for any taxable year, we intend to provide to a U.S. Holder such information as the Internal Revenue Service ("IRS") may require, including a PFIC annual information statement, in order to enable the U.S. Holder to make and maintain a "qualified electing fund" election. For a more detailed explanation of the tax consequences of PFIC classification to U.S. Holders, see the section of this Annual Report entitled "Material U.S. Federal Income Tax Considerations." This paragraph is qualified in its entirety by the discussion under that heading. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have an adverse effect on our business.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") and the rules and regulations promulgated by the SEC to implement Section 404, we are required to include in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting. The assessment must include disclosure of any material weakness in our internal control over financial reporting identified by management.

As part of the evaluation undertaken by management pursuant to Section 404, our management concluded that our internal control over financial reporting was effective as of December 31, 2022. However, if we fail to maintain an effective system of disclosure controls or internal controls over financial reporting, we may discover material weaknesses that we would then be required to disclose. Any material weaknesses identified in our internal controls could have an adverse effect on

our business. We may not be able to accurately or timely report on our financial results, and we might be subject to investigation by regulatory authorities. This could result in a loss of investor confidence in the accuracy and completeness of our financial reports, which may have an adverse effect on our stock price.

No evaluation process can provide complete assurance that our internal controls will detect and correct all failures within our Company to disclose material information otherwise required to be reported. The effectiveness of our controls and procedures could also be limited by simple errors or faulty judgments. In addition, if we continue to expand, through either organic growth or through acquisitions (or both), the challenges involved in implementing appropriate controls will increase and may require that we evolve some or all of our internal control processes. Under applicable SEC rules, our management's assessment of the effectiveness of our internal control over financial reporting are not attested to by our registered public accounting firm.

It is also possible that the overall scope of Section 404 may be revised in the future, thereby causing ourselves to review, revise or reevaluate our internal control processes, which may result in the expenditure of additional human and financial resources.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have an operating lease in Research Triangle Park, North Carolina utilizing small space within a commercial building. The operating lease has payments of $400 per month with no scheduled increases. This operating lease is terminable with 30 days' notice and has no penalties or contingent payments due.

On January 23, 2020, we entered into an Office Service Agreement (the "Office Service Agreement") with Regus to lease office space at in Hoboken, New Jersey. Per the terms of the Office Service Agreement, the monthly rent payments are $1,150. The Office Service Agreement had an initial term of January 27, 2020 to July 31, 2020 and thereafter automatically renews for successive six-month periods. Either party is able to terminate the agreement by providing no less than three months' advance written notice of termination.

Item 3. Legal Proceedings

Chapman v. Fennec Pharmaceuticals Inc. et al.

On September 3, 2020, plaintiff Jim Chapman filed a putative federal securities class action lawsuit against the Company, our Chief Executive Officer, Rostislav Raykov, and Chief Financial Officer, Robert Andrade, in the United States District Court for the Middle District of North Carolina, captioned *Chapman v. Fennec Pharmaceuticals Inc. et al*., Case No. 1:20-cv-00812. The complaint alleged that prior to our August 10, 2020 receipt of a CRL from the FDA concerning our NDA for PEDMARK®, defendants made materially false or misleading statements and failed to disclose material facts about our third-party PEDMARK® product manufacturing facility and the impact the facility would have on regulatory approval for PEDMARK®. On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our Board of Directors as defendants, asserts a putative class period from December 20, 2018 through August 10, 2020, makes allegations similar to those in the original complaint, claims the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, and seeks an unspecified amount of compensatory damages and attorneys' fees and costs.

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

On March 30, 2022, lead plaintiff filed a motion for post judgment relief, seeking leave to file a second amended complaint. In his proposed second amended complaint, lead plaintiff seeks to add allegations stemming from the receipt of a second CRL following our resubmission of our NDA for PEDMARK®, which we received on November 29, 2021, among other things. Defendants filed an opposition to plaintiff's motion for post judgment relief on April 20, 2022. On May 4, 2022, lead plaintiff submitted a reply in support of his motion. On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it has approved PEDMARK®. On October 18, 2022, lead plaintiff filed his opposition to request for judicial notice. On October 21, 2022, defendants filed a reply in support of the request for judicial notice. On February 15, 2023, the Magistrate Judge recommended the motion for post judgment relief be denied. Lead plaintiff filed no timely objection to the recommendation, and on March 2, 2023, the U.S. District Court Judge issued an order adopting the Magistrate Judge's recommendation, denying the motion for post judgment relief, and entering judgment for defendants.

We believe that this lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of December 31, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Fisher v. Fennec Pharmaceuticals Inc. et al.

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

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

On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it approved PEDMARK® On September 30, 2022, lead plaintiff filed an opposition to the request for judicial notice. On October 6, 2022, defendants filed a reply in support of the request for judicial notice. On October 12, 2022, the U.S. District Court Judge issued a memorandum opinion and order dismissing the amended complaint in its entirety and with prejudice, and on October 14, 2022, entered judgment. Lead plaintiff had until November 14, 2022 to file a notice of appeal and did not file a notice of appeal.

We believe that the lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of December 31, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

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

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed two petitions for inter partes review ("IPR") with the Patent Trial and Appeal Board ("PTAB") of the USPTO. In its petitions, Hope seeks to invalidate our U.S. Patent No. 10,596,190 ("US '190 Patent"), which is exclusively in-licensed from Oregon Health & Science University

("OHSU") and relates to a method of using our PEDMARK® product, and our U.S. Patent No. 10,792,363 ("US '363 Patent"), which relates to an anhydrous form of STS and its method of manufacture, which is the active pharmaceutical ingredient in our PEDMARK® product. The US '190 Patent was issued on March 24, 2020. The US '363 Patent was issued on October 6, 2020.

On January 11, 2022, OHSU filed a Request for Supplemental Examination of US '190 Patent (Control No. 96.000,390) requesting the consideration by the Central Re-examination Unit ("CRU") of the USPTO of certain prior art references, including references cited by Hope in its Petition for IPR that are relevant to the granted claim of the patent. On January 28, 2022, the CRU issued a Supplemental Examination Certificate, identified a Substantial New Question ("SNQ") on the patentability of the US '190 Patent claims, and ordered a Reexamination of US '190 Patent on March 9, 2022. On May 9, the PTAB granted Hope Medical's Petition to Institute the IPR against the US '190 Patent and a stayed the US '190 Patent Reexamination pending the result of the US '190 Patent IPR. On August 12, 2022, OHSU filed a Motion to Amend the single claim of the US '190 Patent in the IPR to focus on the treatment of medulloblastoma. On December 5, 2022, OHSU filed a Revised Motion to Amend the single claim of the US '190 Patent. We expect a decision in the '190 Patent IPR in May 2023, which can be appealed by the losing party.

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

On approval of PEDMARK®, we listed the '728 and the '190 patents in the FDA Orange Book. We were granted Orphan Drug Exclusivity in January 2023 for the use of PEDMARK® in the indication to reduce the risk of ototoxicity, or hearing loss, associated with cisplatin use in pediatric patients one month of age and older with localized, non-metastatic solid tumors. We plan to pursue PUMA upon approval of the MAA, which would allow for 10 years of market exclusivity upon PUMA approval.

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

CIPLA Litigation

On December 1, 2022, we received a letter dated November 30, 2022, notifying us that CIPLA submitted to the FDA an ANDA for a generic version of PEDMARK® (sodium thiosulfate solution) that contains Paragraph IV certifications with respect to two of our patents covering PEDMARK®, '190, expiration date May 2038; and '728, expiration date May 2039. 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 thiousulfate 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. 3:23-cv-00123), for infringement of the '190 Patent and the '728 Patent. The suit is ongoing.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common shares currently trade in the U.S. on the Nasdaq Capital Market under the trading symbol "FENC" and in Canada on the TSX under the trading symbol "FRX".

Record Holders

As of March 27, 2023, there were approximately 27 shareholders of record of our common shares, one of which was Cede & Co., a nominee for Depository Trust Company, and one of which was The Canadian Depository for Securities Limited ("CDS"). All of our common shares held by brokerage firms, banks and other financial institutions in the U.S. or Canada as nominees for beneficial owners are considered to be held of record by Cede & Co. and CDS, respectively; in respect of brokerage firms, banks and other financial institutions located in Canada. Cede & Co. and CDS are each considered to be one shareholder of record.

Dividend Policy

We have never declared or paid cash dividends on our common shares. We currently expect to retain future earnings, if any, for use in the operation and expansion of business and do not anticipate paying any cash dividends in the foreseeable future.

Material United States Federal and Canadian Income Tax Consequences

Material U.S. Federal Income Tax Considerations

The following summary describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) of acquiring, owning, and disposing of our common shares, subject to the qualifications set forth herein.

General

Tax Consequences Not Addressed

This summary does not address all potential U.S. federal income tax considerations that may be relevant to a particular U.S. Holder. In addition, this summary does not take into account the individual facts and circumstances that may affect the U.S. federal income tax consequences to a particular U.S. Holder, including specific tax consequences under an applicable income tax treaty. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any U.S. Holder. This summary does not address any U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, or non-U.S. tax considerations, and does not discuss tax reporting requirements that may be applicable to any particular U.S. Holder. Each prospective investor should consult a professional tax advisor with respect to the U.S. federal income, U.S. alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences of acquiring, owning, and disposing of our common shares.

Authorities

This summary is based upon the provisions of the United States Internal Revenue Code (the "Code"), the United States Treasury Regulations (whether final, temporary, or proposed) promulgated thereunder, the Convention Between Canada and the United States of America with Respect to Taxes on Income and on Capital, signed September 26, 1980, as amended (the "Canada-U.S. Tax Convention"), and administrative rulings and judicial decisions interpreting the Code and the United States Treasury Regulations, all as currently in effect, and all subject to differing interpretations or change, possibly on a retroactive basis. We have not sought, and will not seek, a ruling from the IRS regarding any matter discussed herein,

and no assurance can be given that the IRS would not assert, or that a court would not sustain, a position that is different from, and contrary to, the positions taken in this summary. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation.

U.S. Holders

For purposes of this summary, the term "U.S. Holder" means a beneficial owner of our common shares that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States (as determined under U.S. federal income tax rules);
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (i) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (ii) has a valid election in effect under applicable United States Treasury Regulations to be treated as a U.S. person.

An individual may be a resident for U.S. federal income tax purposes in any calendar year if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with the current calendar year. For purposes of this calculation, all of the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

Non-U.S. Holders Not Addressed

For purposes of this summary, a "non-U.S. Holder" is a beneficial owner of common shares that is not a U.S. Holder and is not a partnership for U.S. federal income tax purposes. This summary does not address the U.S. federal income tax consequences to non-U.S. Holders of acquiring, owning, and disposing our common shares. Each non-U.S. Holder investor should consult a professional tax advisor with respect to the U.S. federal income, U.S. alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences of acquiring, owning, and disposing of our common shares.

Certain U.S. Holders Not Addressed

This summary does not address the U.S. federal income tax considerations applicable U.S. Holders that are subject to special provisions under the Code, including, but not limited to, U.S. Holders that:

- are tax-exempt organizations, qualified retirement plans, individual retirement accounts, or other tax-deferred accounts;
- are financial institutions, underwriters, insurance companies, real estate investment trusts, or regulated investment companies;
- are broker-dealers, dealers, or traders in securities or currencies that elect to apply a mark-to-market accounting method;
- have a "functional currency" other than the U.S. dollar;
- own common shares as part of a straddle, hedging transaction, conversion transaction, constructive sale, or other arrangement involving more than one position;

- acquired common shares in connection with the exercise of employee stock options or otherwise as compensation for services;
- hold common shares other than as a capital asset within the meaning of section 1221 of the Code (generally, property held for investment purposes);
- are partnerships or other "pass-through" entities for U.S. federal income tax purposes (or investors in such partnerships or entities);
- own, have owned, or will own (directly, indirectly, or by attribution) 10% or more of the total combined voting power of the outstanding shares of your company;
- are U.S. expatriates who are former citizens or long-term residents of the United States;
- have been, are, or will be residents or deemed to be residents in Canada for purposes of the Income Tax Act (Canada) (the "Tax Act");
- use or hold, will use or hold, or that are or will be deemed to use or hold common shares in connection with carrying on a business in Canada;
- are persons whose common shares constitute "taxable Canadian property" under the Tax Act; or
- have a permanent establishment in Canada for the purposes of the Canada-U.S. Tax Convention.

U.S. Holders that are subject to special provisions under the Code, including, but not limited to, U.S. Holders described immediately above, should consult their own tax advisors regarding the U.S. federal income, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences of acquiring, owning, and disposing of our common shares.

The following summary is not a substitute for careful tax planning and advice. U.S. Holders of common shares are urged to consult their own tax advisors concerning the U.S. federal income tax consequences of the issues discussed herein, in light of their particular circumstances, as well as any considerations arising under the laws of any foreign, state, local, or other taxing jurisdiction.

General Rules Applicable to the Ownership and Disposition of Common Shares

The following discussion describes the general rules applicable to the ownership and disposition of the common shares but is subject in its entirety to the special rules described below under the headings entitled "Tax Consequences if We Are a Passive Foreign Investment Company" and "Tax Consequences if We are a Controlled Foreign Corporation."

Distributions on Common Shares

The gross amount of any distribution (including amounts, if any, withheld in respect of Canadian withholding tax) actually or constructively received by a U.S. Holder with respect to our common shares will be taxable to the U.S. Holder as a dividend to the extent of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions to a U.S. Holder in excess of earnings and profits will be treated first as a return of capital that reduces a U.S. Holder's tax basis in such common shares (thereby increasing the amount of gain or decreasing the amount of loss that a U.S. Holder would recognize on a subsequent disposition of our common shares), and then as gain from the sale or exchange of such common shares (see "Sale or Other Taxable Disposition of Our Common Shares"). The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution. In the event we make distributions to holders of common shares, we may or may not calculate our earnings and profits under U.S. federal income tax principles. If we do not do so, any distribution may be required to be regarded as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain. The amount of the dividend will generally be treated as foreign-source dividend income to U.S. Holders.

Non-corporate U.S. Holders, including individuals, will generally be eligible for the preferential U.S. federal rate on "qualified dividend income," provided that we are a "qualified foreign corporation," the stock on which the dividend is paid is held for a minimum holding period, and other requirements are satisfied. A "qualified foreign corporation" includes a foreign corporation that is not a PFIC in the year of the distribution or in the prior taxable year and that is eligible for the benefits of an income tax treaty with the United States that contains an exchange of information provision and has been determined by the United States Treasury Department to be satisfactory for purposes of the legislation (such as the Canada-U.S. Tax Convention).

Distributions to U.S. Holders generally will not be eligible for the "dividends received deduction" generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations.

Sale or Other Taxable Disposition of Our Common Shares

Upon the sale, exchange, or other taxable disposition of our common shares, a U.S. Holder generally will recognize gain or loss equal to the difference between the amount realized upon the sale, exchange, or other disposition and such U.S. Holder's tax basis in such common shares sold or otherwise disposed of. If the U.S. holder receives Canadian dollars in the transaction, the amount realized will be the U.S. dollar value of the Canadian dollars received, which is determined for cash basis taxpayers on the settlement date for the transaction and for accrual basis taxpayers on the trade date (although accrual basis taxpayers can also elect the settlement date). A U.S. Holder's tax basis in common shares generally will be such holder's U.S. dollar cost for such common shares. Gain or loss recognized on such sale or other disposition generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares have been held for more than one year.

Preferential tax rates currently apply to long-term capital gain of a U.S. Holder that is an individual, estate, or trust. There are currently no preferential tax rates for long-term capital gain of a corporate U.S. Holder. Deductions for capital losses are subject to significant limitations under the Code. The gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes.

Additional Medicare Tax on Net Investment Income

Certain U.S. Holders that are individuals, estates, or trusts (other than trusts that are exempt from tax) are subject to a tax of 3.8% on "net investment income" (or undistributed "net investment income," in the case of estates and trusts) for each taxable year, with such tax applying to the lesser of such income or the excess of such person's adjusted gross income (with certain adjustments) over a specified amount. Net investment income includes dividends on the common shares and net gains from the disposition of the common shares.

U.S. Holders that are individuals, estates, or trusts should consult their own tax advisors regarding the applicability of this tax to any of their income or gains in respect of the common shares.

Receipt of Foreign Currency

The amount of any distribution paid to a U.S. Holder in foreign currency, or on the sale, exchange, or other taxable disposition of common shares, generally will be equal to the U.S. dollar value of such foreign currency based on the exchange rate applicable on the date of receipt (regardless of whether such foreign currency is converted into U.S. dollars at that time). If the foreign currency received is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a tax basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any U.S. Holder who converts or otherwise disposes of the foreign currency after the date of receipt may have a foreign currency exchange gain or loss that would be treated as ordinary income or loss, and generally will be U.S. source income or loss for foreign tax credit purposes. Different rules apply to U.S. Holders who use the accrual method of tax accounting. Each U.S. Holder should consult its own U.S. tax advisors regarding the U.S. federal income tax consequences of receiving, owning, and disposing of foreign currency.

Foreign Tax Credit

Subject to the PFIC rules discussed below, a U.S. Holder that pays (whether directly or through withholding) Canadian income tax with respect to dividends paid on the common shares generally will be entitled, at the election of such U.S.

Holder, to receive either a deduction or a credit for such Canadian income tax paid. Generally, a credit will reduce a U.S. Holder's U.S. federal income tax liability on a dollar-for-dollar basis, whereas a deduction will reduce a U.S. Holder's income that is subject to U.S. federal income tax. This election is made on a year-by-year basis and applies to all foreign taxes paid (whether directly or through withholding) by a U.S. Holder during a year.

Complex limitations apply to the foreign tax credit, including the general limitation that the credit cannot exceed the proportionate share of a U.S. Holder's U.S. federal income tax liability that such U.S. Holder's "foreign source" taxable income bears to such U.S. Holder's worldwide taxable income. In applying this limitation, a U.S. Holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." Generally, dividends paid by a foreign corporation (including constructive dividends) should be treated as foreign source for this purpose, and gains recognized on the sale of stock of a foreign corporation by a U.S. Holder should be treated as U.S. source for this purpose, except as otherwise provided in an applicable income tax treaty, and if an election is properly made under the Code. However, the amount of a distribution with respect to the common shares that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for Canadian federal income tax purposes, resulting in a reduced foreign tax credit allowance to a U.S. Holder. In addition, this limitation is calculated separately with respect to specific categories of income. The foreign tax credit rules are complex, and each U.S. Holder should consult its own U.S. tax advisors regarding the foreign tax credit rules.

Information Reporting and Backup Withholding

Under U.S. federal income tax law, certain categories of U.S. Holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. For example, certain U.S. Holders who hold certain "specified foreign financial assets" that exceed certain thresholds are required to report information relating to such assets. The definition of "specified foreign financial assets" generally includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-U.S. person, any financial instrument or contract held for investment that has an issuer or counterparty other than a U.S. person, and any interest in a foreign entity. U.S. Holders may be subject to these reporting requirements unless their common shares are held in an account at certain financial institutions. Significant penalties may apply for failure to satisfy applicable reporting obligations.

Distributions paid with respect to common shares and proceeds from a sale, exchange, or redemption of common shares made within the United States or through certain U.S.-related financial intermediaries may be subject to information reporting to the IRS and possible U.S. backup withholding (at a rate of 28%). Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct U.S. taxpayer identification number and makes any other required certification on IRS Form W-9 or that is a corporation or other entity that is otherwise exempt from backup withholding. Each U.S. Holder should consult its own tax advisors regarding the application of the U.S. information reporting and backup withholding rules. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability, and such holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

The discussion of reporting requirements set forth above is not intended to constitute a complete description of all reporting requirements that may apply to a U.S. Holder. A failure to satisfy certain reporting requirements may result in an extension of the time period during which the IRS can assess a tax and, under certain circumstances, such an extension may apply to assessments of amounts unrelated to any unsatisfied reporting requirement. U.S. Holders should consult with their own tax advisors regarding their reporting obligations, if any, as a result of their acquisition, ownership, or disposition of our common shares.

Tax Consequences if We are a Passive Foreign Investment Company

A foreign corporation generally will be treated as a PFIC if, after applying certain "look-through" rules, either (i) 75% or more of its gross income is passive income or (ii) 50% or more of the average value of its assets is attributable to assets that produce or are held to produce passive income. Passive income for this purpose generally includes dividends, interest, rents, royalties and gains from securities and commodities transactions. The look-through rules require a foreign corporation that owns at least 25% by value of the stock of another corporation to treat a proportionate amount of assets and income as held or received directly by the foreign corporation.

We have not made the analysis necessary to determine whether or not we are currently a PFIC or whether we have ever been a PFIC. There can be no assurance that we are not, have never been or will not in the future be a PFIC. If we were to be treated as a PFIC, any gain recognized by a U.S. shareholder upon the sale (or certain other dispositions) of our common shares (or the receipt of certain distributions) generally would be treated as ordinary income, and a U.S. shareholder may be required, in certain circumstances, to pay an interest charge together with tax calculated at maximum rates on certain "excess distributions," including any gain on the sale or certain dispositions of our common shares. In order to avoid this tax consequence, a U.S. shareholder (i) may be permitted to make a "qualified electing fund" election, in which case, in lieu of such treatment, such shareholder would be required to include in its taxable income certain undistributed amounts of our income or (ii) may elect to mark-to-market our common shares and recognize ordinary income (or possible ordinary loss) each year with respect to such investment and on the sale or other disposition of the common shares. Additionally, if we are deemed to be a PFIC, a U.S. shareholder who acquires our common shares from a decedent will be denied the normally available step-up in tax basis to fair market value for the common shares at the date of the death and instead will have a tax basis equal to the decedent's tax basis if lower than fair market value. Neither we nor our advisors have the duty to or will undertake to inform U.S. shareholders of changes in circumstances that would cause us to become a PFIC. U.S. shareholders should consult their own tax advisors regarding the application of the PFIC rules including eligibility for and the manner and advisability of making certain elections in the event we are determined to be a PFIC at any point in time. We intend to take the action necessary for a U.S. shareholder to make a "qualified electing fund" election in the event we are a PFIC.

Further, excess distributions treated as dividends, gains treated as excess distributions and mark-to-market inclusions and deductions, all under the PFIC rules discussed above, are all included in the calculation of net investment income for purposes of the 3.8% tax described above under the subheading entitled "Additional Medicare Tax on Net Investment Income". United States Treasury Regulations provide, subject to the election described in the following paragraph, that solely for purposes of this additional tax, distributions of previously taxed income will be treated as dividends and included in net investment income subject to the additional 3.8% tax. Additionally, to determine the amount of any capital gain from the sale or other taxable disposition of common shares that will be subject to the additional tax on net investment income, a U.S. Holder who has made a "qualified electing fund" election will be required to recalculate its basis in the common shares excluding basis adjustments resulting from the "qualified electing fund" election. Alternatively, a U.S. Holder may make an election which will be effective with respect to all interests in a PFIC for which a "qualified electing fund" election has been made and which is held in that year or acquired in future years. Under this election, a U.S. Holder pays the additional 3.8% tax on income inclusions resulting from the "qualified electing fund" election and on gains calculated after giving effect to related tax basis adjustments.

Tax Consequences if We are a Controlled Foreign Corporation

A foreign corporation will be treated as a "controlled foreign corporation" ("CFC") for U.S. federal income tax purposes if, on any day during the taxable year of such foreign corporation, more than 50% of the equity interests in such corporation, measured by reference to the combined voting power or value of the equity of the corporation, is owned directly or by application of the attribution and constructive ownership rules of Sections 958(a) and 958(b) of the Code by United States Shareholders. For this purpose, a "United States Shareholder" is any United States person that possesses directly, or by application of the attribution and constructive ownership rules of Sections 958(a) and 958(b) of the Code, 10% or more of the combined voting power of all classes of equity in such corporation or 10% or more of the total value of shares of all classes in such corporation. If a foreign corporation is a CFC on any day during any taxable year, each United States Shareholder of our Company who owns, directly or indirectly, our common shares on the last day of the taxable year on which we are a CFC will be required to include in its gross income for United States federal income tax purposes its pro rata share of our "Subpart F income," even if the Subpart F income is not distributed. Subpart F income generally includes passive income but also includes certain related party sales, manufacturing and services income.

In addition to the inclusion of "Subpart F income" of a CFC in the gross income of a United States Shareholder, there may be exposure to an additional tax under the recently enacted Global Intangible Low Tax Income regime ("GILTI"). Specifically, the GILTI rules impose an annual minimum tax on U.S. Holders of their share of GILTI income generated through CFCs. This GILTI income very generally equals a CFC's income over a 10% return on the CFCs tangible depreciable trade or business assets. The GILTI tax is 10.5% (until 2026 and 13.12% for tax years after) on U.S. Holders who are C corporations, as they are entitled to a 50% deduction (37.5% after 2025) of the GILTI income as well as a reduced foreign tax credit on foreign taxes paid on the GILTI income. U.S. Holders who are individuals, estates or trusts may pay substantially more tax on GILTI income, as they are subject to ordinary tax rates (ranging from 10% to 37% plus

the net investment income tax of 3.8%). Such U.S. Holders are not entitled to a deduction on GILTI income or a reduced foreign tax credit. There is, however, an election available to such U.S. Holders to mitigate the tax impact.

If we are a CFC, the PFIC rules set forth above, even if we are otherwise considered to be a PFIC, will not be applicable.

United States persons who might, directly, indirectly or constructively, acquire 10% or more of our common shares, and therefore might be a United States Shareholder, should consider the possible application of the CFC rules and GILTI rules and consult a tax advisor with respect to such matters.

Material Canadian Federal Income Tax Considerations

Non-Residents of Canada

The following portion of the summary is generally applicable to a U.S. Holder. Special rules, which are not discussed in this summary, may apply to a U.S. Holder that is an insurer that carries on an insurance business in Canada and elsewhere.

Disposition of Common Shares

Upon the disposition by a U.S. Holder of common shares in our Company, the U.S. Holder will not be subject to tax under the Tax Act in respect of any capital gain realized unless the common shares disposed of constitutes "taxable Canadian property" of the U.S. Holder and the U.S. Holder is not entitled to relief under an applicable tax treaty or convention. Common shares will generally not constitute "taxable Canadian property" of such U.S. Holder unless at any time in the preceding 60 months both of the following statements were true: (a) the U.S. Holder, together with either (i) persons with whom the U.S. Holder does not deal at arm's length or (ii) partnerships in which the U.S. Holder or a person in (a) directly or indirectly hold membership interests, held shares and/or rights to acquire shares representing 25% or more of the issued shares of any class of our capital stock; and (b) more than 50% of the fair market value of our common stock was derived directly or indirectly from one or any combination of (i) real or immovable property situated in Canada, (ii) Canadian resource properties, (iii) timber resource properties, and (iv) options in respect of, or interests in, or for civil law rights in, property described in any of (i) to (iii).

U.S. Holders whose common shares constitute "taxable Canadian property" should consult their own tax advisors for advice having regard to their particular circumstances.

Dividends Paid on Common Shares

Dividends paid, credited or deemed to have been paid or credited on our common shares held by a U.S. Holder will be subject to a Canadian withholding tax under the Tax Act at a rate of 25% of the gross amount of the dividends, subject to reduction by any applicable tax convention. Under the tax convention between Canada and the United States (the "Tax Treaty"), the rate of withholding tax on dividends generally applicable to U.S. Holders who beneficially own the dividends is reduced to 15%. In the case of U.S. Holders that are corporations that beneficially own at least 10% of our voting shares, the rate of withholding tax on dividends generally is reduced to 5%. So-called "fiscally transparent" entities, such as United States limited liability companies, or LLCs, are not entitled to rely on the terms of the Tax Treaty, however a member of such entity will be considered to have received the dividend directly and to benefit from the reduced rates under the Tax Treaty, where the member is considered under U.S. taxation law to have derived the dividend through that entity and by reason of the entity being a fiscally transparent entity, the treatment of the dividend is the same as its treatment would be if the amount had been derived directly by the member. Members of such entities are regarded as holding their proportionate share of our common shares held by the entity for the purposes of the Tax Treaty.

Item 6. Reserved

Not applicable.

Item 7. 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 consolidated financial statements and related notes appearing at the end of this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" section of this Annual Report, 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.

Overview

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

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

Further, 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 currently have three patents listed for PEDMARK® in the FDA's Orange Book which are the "190", "728" and "984" patents. The "190" patent is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using our PEDMARK® product. The "190" expires in 2038 and the "728" and "984" patents expire in 2039, respectively, unless held invalid or unenforceable by a court or final jurisdiction. Further, in January 2023, the USPTO issued Notices of Allowance to us for one additional patent applications that cover the PEDMARK® pharmaceutical formulation. We expect this additional U.S. patent to issue in Q1 of 2023 or Q2 of 2023. This patent will expire in 2039, unless held invalid or unenforceable by a court of final jurisdiction. We are also pursuing additional patent applications in both the U.S. and internationally for PEDMARK®.

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

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

In August 2018, the Pediatric Committee ("PDCO") of the European Medicines Agency ("EMA") accepted our pediatric investigation plan ("PIP") for sodium thiosulfate with the trade name Pedmarqsi for the condition of the prevention of platinum-induced hearing loss. An accepted PIP is a prerequisite for filing a Marketing Authorization Application ("MAA") for any new medicinal product in Europe. The indication targeted by our PIP is for the prevention of platinum-

induced ototoxic hearing loss for standard risk hepatoblastoma ("SR-HB"). Additional tumor types of the proposed indication will be subject to the Committee for Medicinal Products for Human Use ("CHMP") assessment at the time of the MAA. No deferred clinical studies were required in the positive opinion given by PDCO. We were also advised that sodium thiosulfate (tradename to be determined) is eligible for submission of an application for a PUMA. A PUMA is a dedicated marketing authorization covering the indication and appropriate formulation for medicines developed exclusively for use in the pediatric population and provides market protection up to 10 years. Therefore, this decision allows us to proceed with the submission of a PUMA in the European Union ("EU") with incentives of automatic access to the centralized procedure and up to 10 years of market protection. In February 2020, we announced that we had submitted a MAA for the prevention of ototoxicity induced by cisplatin chemotherapy patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. The EMA continues its review of our MAA.

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

We generated a net loss of approximately $23.7 million for the fiscal year ended December 31, 2022, and a net loss of $17.4 million for the fiscal year ended December 31, 2021. As of December 31, 2022, our accumulated deficit was approximately $203.2 million ($179.5 million at December 31, 2021).

We believe that our cash and cash equivalents as of December 31, 2022, which totaled $23.8 million, cash from product sales, plus the remaining Petrichor Financing of $20 million in convertible notes subject to mutual agreement between the Company and Petrichor (see Note 1 and Note 7 to consolidated financial statements contained elsewhere in this report), will be sufficient to meet our cash requirements through at least the next twelve months. Our projections of our capital requirements are subject to substantial uncertainty, and more capital than we currently anticipate may be required thereafter. To finance our continuing operations, we may need to raise substantial additional funds through either the sale of additional equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out-license or sale of certain aspects of our intellectual property portfolio or from other sources. We may not be able to raise the necessary capital, or such funding may not be available on financially acceptable terms if at all. If we cannot obtain adequate funding in the future, we might be required to further delay, scale back or eliminate certain research and development studies, consider business combinations, or even shut down some, or all, of our operations.

Our operating expenses will depend on many factors, including the progress of our commercialization efforts and efficiency of our operations and current resources. Our research and development expenses, which include expenses associated with our clinical trials, drug manufacturing to support clinical programs, consulting fees, sponsored research costs, toxicology studies, license fees, milestone payments, and other fees and costs related to the comercialization 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

Fiscal 2022 versus Fiscal 2021

In thousands of U.S. Dollars	Fiscal Year Ended December 31, 2022	%	Fiscal Year Ended December 31, 2021	%	Increase (Decrease)
PEDMARK product sales, net	$ 1,535		$ —		$ 1,535
Cost of product sales	(86)		—		(86)
Gross profit	1,449		—		1,449
Operating expenses:					
Research and development	3,531	15 %	4,981	29 %	(1,450)
Selling and marketing	2,785	12 %	—	- %	2,785
General and administrative	17,722	74 %	12,242	71 %	5,480
Total operating expense	24,038	100 %	17,223	100 %	6,815
Loss from operations	22,589		17,223		5,280
Unrealized loss on securities	(184)		(25)		(159)
Amortization expense	(149)		(16)		(133)
Interest expense	(978)		(126)		(852)
Unrealized foreign exchange loss	(9)		(10)		1
Interest income	195		54		141
Net loss	**$ (23,714)**		**$ (17,346)**		**$ (5,430)**

- Commercial launch of PEDMARK® commenced in October 2022. The Company recorded net product sales of $1.54 million in fiscal 2022. The Company recorded discounts and allowances against sales in the amount of $0.2 million and cost of products sold of $0.1 million. The Company had gross profit of $1.4 million for fiscal year ended 2022. In fiscal 2021, the Company had no revenues.

- Research and development expense decreased by $1.5 million in fiscal 2022 as compared to fiscal 2021. The Company reduced research and development costs when it received FDA approval of PEDMARK®. The majority of traditional research and development expenses associated with PEDMARK® are now recorded as general and administrative expenses or capitalized into inventory and eventually recorded to costs of product sales.

- The Company began incurring selling and marketing expenses when it expanded its payroll to include an internal salesforce. Selling and marketing expenses include distribution costs, logistics, shipping and insurance, advertising, wages commissions and out-of-pocket expenses. The Company recorded $2.8 million in selling and marketing expenses in fiscal 2022.

- There was a $5.5 million increase in general and administrative expenses in fiscal 2022 compared to fiscal 2021. Payroll and benefits related expenses rose by $4.0 million in fiscal 2022 compared to fiscal 2021. There was an increase in legal costs of $1.4 million in fiscal 2022 over fiscal 2021. This net increase is comprised of an increase in $0.2 million in class action suit defense, a decrease in general legal expense of $0.2 million and an increase of $1.4 million in intellectual property litigation. Pre-commercialization activities rose by $0.4 million in fiscal 2022 over fiscal 2021. Non-cash expenses associated with equity remuneration increased by $0.2 million.

- The value of our Processa shares declined by $0.2 million for the year ended December 31, 2022. For fiscal year ended December 31, 2021, there was a gain of $0.03 million. 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 was up $0.1 million in fiscal 2022, as we wrote off the entire capitalized amount associated with the Bridge Bank Loan and Security Agreement origination costs but replaced it with the Petrichor Opportunities Fund I LP Senior Secured Securities Notes. The increase in amortization relates to the relative size of the deferred asset created by the capitalization of the loan origination and access fees.

- Other losses increased by $0.6 million, driven mainly by interest on long-term debt.

- Interest income increased in fiscal 2022 as compared to fiscal 2021 by $0.1 million, due to higher average balances and sharply increased rates on money market accounts for the comparable periods.

Quarterly Information

The following table presents selected consolidated financial data for each of the last eight quarters through December 31, 2022, 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
March 31, 2021	$ (4,733)	$ (0.18)	$ (0.18)
June 30, 2021	(4,001)	(0.15)	(0.15)
September 30, 2021	(4,185)	(0.16)	(0.16)
December 31, 2021	(4,427)	(0.18)	(0.18)
March 31, 2022	(3,696)	(0.14)	(0.14)
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)

Quarter ended December 31, 2022 versus 2021

In thousands of U.S. Dollars	Quarter Ended December 31, 2022	%	Quarter Ended December 31, 2021	%	Increase (Decrease)
PEDMARK product sales, net	$ 1,535		$ —		$ 1,535
Cost of product sales	(86)		—		(86)
Gross profit	1,449		—		1,449
Operating expenses:					
Research and development	117	2 %	523	36 %	(406)
Selling and marketing	2,785	37 %	—	— %	2,785
General and administration	4,682	62 %	3,684	64 %	998
Total operating expense	7,584	100 %	4,207	100 %	3,377
Loss from operations	6,135		4,207		1,928
Unrealized (loss)/gain on securities	(58)		(162)		104
Interest income	153		13		140
Amortization expense	(70)		(8)		(62)
Interest expense	(744)		(62)		(682)
Other (loss), net	(3)		(1)		(2)
Net loss	**$ (6,857)**		**$ (4,427)**		**$ (2,430)**

Revenues reported in the three months ended December 31, 2022, represent product sales of PEDMARK®. We announced product launch of PEDMARK® on October 17, 2022. We reported a loss from operations of $6.1 million for the three months ended December 31, 2022, compared to a loss from operations of $4.2 million for the same period in 2021. Research and development expenses totaled $0.1 million for the three months ended December 31, 2022, down by $0.4 million over the same period in 2021. The Company recorded selling and marketing expenses of $2.8 million in the quarter ended December 31, 2022. General and administrative expenses increased by $1.0 million in the three months ended December 31, 2022, as compared to the same period in 2021. There was an increase of $795 related to product launch activities, $334 related to professional fees, $89 in payroll and benefits and an $87 increase in miscellaneous items. These increases were offset by a decrease in non-cash equity expenses of $318. There was an unrealized loss of $0.06 million on the Processa shares for quarter ended December 31, 2022. The Processa shares will be marked to market at each balance sheet date. Interest income was up $0.14 million for the quarter ended December 31, 2022 compared to the same period a year prior. This was driven by higher daily balances and higher interest rates. Amortization and interest expenses were up

$0.74 million for the quarter ended December 31, 2022 over the same period in 2021. The vast majority of this is interest and is driven by larger debt load and higher interest rates.

Selected Asset and Liability Data (thousands):	As at December 31, 2022	As at December 31, 2021
Cash and equivalents	$ 23,774	$ 21,100
Other current assets	2,954	1,287
Current liabilities	(4,608)	(1,654)
Working capital [1]	22,120	20,733
[1] [Current assets – current liabilities]		
Selected Equity:		
Common stock and additional paid in capital	199,388	194,015
Accumulated deficit	(203,200)	(179,486)
Shareholders' (deficit) equity	(2,569)	15,772

Liquidity and Capital Resources

- There was a $2.7 million increase in cash and cash equivalents between December 31, 2022 and December 31, 2021. The net increase was the result of cash operating expenses, offset by the net $20.0 million received from the Petrichor note and $0.9 million received from the exercise of 273 options. During the period ended December 31, 2022, cash for operations was used mainly on the pre-commercialization activities of PEDMARK® prior to FDA approval and then commercialization activities post NDA approval.

- The increase in other current assets of $1.7 million between December 31, 2021 and December 31, 2022 primarily relates to an increase of $2.1 million in inventory and accounts receivable offset by $0.4 million decrease in the value of Processa shares and prepaid assets.

- Current liabilities at December 31, 2022 increased $3.0 million compared to December 31, 2021. Accounts payable was up $1.6 million over prior year highlighting our post commercialization activity. Accrued expenses were up $1.4 million over prior year primarily due to a $1.3 million increase in anticipated bonus payments and employee paid time off.

- Working capital increased by $1.4 million between December 31, 2022 and December 31, 2021. The increase was a result of cash used in operations offset by net inflow of cash of $20.0 million received from the Petrichor Note, and $0.9 million received from stock option exercises and interest income.

Selected Cash Flow Data (dollars and shares in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021
Net cash used in operating activities	$ (18,058)	$ (14,222)
Net cash provided by investing activities	—	—
Net cash provided by financing activities	20,732	4,978
Net cash flow	$ 2,674	$ (9,244)

The net cash flow used in operating activities for the year ended December 31, 2022 was approximately $18.1 million as compared to $14.2 million in 2021. There was an increase in net loss of $6.4 million in fiscal 2022 compared to fiscal 2021. In 2022 non-cash items added back to net loss increased by $0.5 million over 2021 and net changes in balance sheet accounts added back another $0.2 million over 2021. Net financing activities in 2022 provided approximately $20.7 million from funding of the Petrichor Note, net of fees, and approximately $0.9 million arising from various option exercises.

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.

We had cash and cash equivalents of approximately $23.8 million as of December 31, 2022. We currently anticipate that our available capital resources, including our existing cash and cash equivalents, accounts receivable balances and the remaining $20 million available under the SPA by mutual agreement between the Company and Petrichor, will be sufficient to meet our expected working capital and capital expenditure requirements as our business is currently conducted for at least the next 12 months.

Financial Instruments

We invest excess cash and cash equivalents in high credit quality investments held by financial institutions in accordance with our investment policy designed to protect the principal investment. At December 31, 2022, we had approximately $0.3 million in our cash accounts and $23.5 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 the company is cash flow positive from operations, we have chosen to avoid investments of a trading or speculative nature.

We classify 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 Annual Report.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

None.

Critical Accounting Policies and Estimates

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

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. The following description of critical accounting policies, judgments and estimates should be read in conjunction with our December 31, 2022 consolidated financial statements.

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 December 31, 2022 and 2021, we used the following weighted average assumptions:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected dividend	— %	— %
Risk-free interest rate	1.18 - 3.96 %	1.41 – 1.62 %
Expected volatility	150 - 181 %	122 %
Expected life	5 - 6 years	10 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 as additional paid-in capital.

Outstanding Share Information

Our outstanding comparative share data at December 31, 2022 and December 31, 2021 is as follows (in thousands):

Outstanding Share Type	December 31, 2022	December 31, 2021	Change
Common shares	26,361	26,014	347
Warrants	150	39	111
Stock options	4,539	4,259	280
Total	31,050	30,312	738

Newly Adopted and Recent Accounting Pronouncements

In May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU provides measurement guidance for a modification or an exchange of a freestanding equity classified written call option that is not within the scope of another Topic. The Company adopted the ASU as of January 1, 2022 and its adoption did

not have a significant impact on the Company's consolidated financial statements. The Company will apply the amendments prospectively to modifications or exchanges occurring on or after January 1, 2022.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments – Credit Losses (Topic 326) and subsequently related amendments (ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11 and ASU 2022-02). This guidance replaces the existing incurred loss impairment guidance and establishes a single allowance framework for financial assets carried at amortized cost based on expected credit losses. The estimate of expected credit losses requires the incorporation of historical information, current conditions, and reasonable and supportable forecasts. This ASU will be effective for the year ended December 31, 2023. The Company is currently evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). The new standard eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. This ASU will be effective for the year ended December 31, 2024. The Company is currently evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

In June 2022, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2022-03, Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which (1) clarifies the guidance in Topic 820 on the fair value measurement of an equity security that is subject to contractual restrictions that prohibit the sale of an equity security and (2) requires specific disclosures related to such an equity security. This ASU will be effective for the year ended December 31, 2024. The Company is currently evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Money Market Investments

We maintain an investment portfolio consisting of U.S. or Canadian obligations and bank securities and money market investments in compliance with our investment policy. We do not hold any mortgaged-backed investments in our investment portfolio. Securities must have a minimum Dun & Bradstreet rating of A for bonds or R1 low for commercial paper. The policy also provides for investment limits on concentrations of securities by issuer and maximum-weighted average time to maturity of twelve months. This policy applies to all of our financial resources.

At December 31, 2022, we had $23.5 million in money market investments and savings accounts as compared to $21.0 million at December 31, 2021; these investments typically have minimal risk. We have not experienced any loss or write down of our money market investments for the years ended December 31, 2022 and 2021; however, 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. Our risk associated with fluctuating interest rates on our investments is minimal and not significant to the results of operations. We currently do not use interest rate derivative instruments to manage exposure to interest rate changes. As our main purpose is research and development, we have chosen to avoid investments of a trade or speculative nature.

Foreign Currency Exposure

We are subject to foreign currency risks as we purchase goods and services which are denominated in Canadian dollars. To date, we have not employed the use of derivative instruments; however, we do hold Canadian dollars which we use to pay vendors in Canada and other corporate obligations. At December 31, 2022, we held approximately CAD$0.05.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. A list of the financial statements filed herewith is found at "Index to Financial Statements" on Page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded based on their evaluation as of December 31, 2022 that our "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act are effective. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures also include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer and principal accounting officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in rules promulgated under the Exchange Act, is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and affected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of Consolidated Financial Statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of Consolidated Financial Statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our Consolidated Financial Statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting can also be circumvented by collusion or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process, and it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making its assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in its 2013 *Internal Control — Integrated Framework*. Based on its assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

Because we are a non-accelerated filer and smaller reporting company, Haskell & White LLP, our independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control over financial reporting that occurred during the last fiscal quarter covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Controls

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

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth the name of each of our executive officers and directors, such person's principal occupation or employment, all other positions with us held by such person, if any, the year in which such person became a director of Fennec and such person's age.

Our Board has an Audit Committee, a Compensation Committee, and a Governance Committee. The current members of such committees are noted in the table below:

Name and Province/State and Country of Residence, Position	Current Principal Occupation and Principal Occupation For Previous Five Years	Director Since	Age
Rostislav Raykov, New Jersey, USA Chief Executive Officer, Director	CEO of Fennec Pharmaceuticals Inc.; previously Portfolio Manager at Alchem Partners; previously Portfolio Manager at John Levin & Company	July 2009	46
Robert Andrade, Texas, USA Chief Financial Officer	CFO of Fennec Pharmaceuticals; previously senior analyst at Magnetar Capital; previously Portfolio Manager at Millennium Partners	N/A	47
Chris A. Rallis, North Carolina, USA Director(1)(2)	Executive-in-residence at Pappas Capital; previously CEO of ImmunoBiosciences	August 2011	69
Marco Brughera, Milano, Italy Director(2)(3)	Former Group CEO of Leadiant Biosciences SpA; previously Global Head Rare Disease and R&D at Sigma-tau; VP Preclinical Development at Nerviano Medical Sciences.	August, 2016	67
Adrian J. Haigh, Dublin, Ireland Director(1)(3)	Former SVP, Head of International at PTC Therapeutics; previously Chief Operating Officer at Gentium GmbH; previously Regional VP Commercial Operations at Biogen Idec	April 2014	63
Khalid Islam, Lugano, Switzerland Chairman of Board, Director(1)	Founder and Chairman of Gain Therapeutics ; previously Chairman and CEO of Gentium S.p.A.; previously CEO of Arpida AG	April 2014	67
Jodi A. Cook, PhD South Carolina, USA, Director(2)(3)	CEO of Skylark Bio Inc, Former SVP, Head of Gene Therapy Strategy PTC Therapeutics, Inc, Former COO Agilis Biotherapeutics, Former Assistant Professor of Audiology Mayo Clinic	September 2019	55

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Governance Committee

Rostislav Raykov

Mr. Raykov has served as a director of Fennec since July 2009 and as Chief Executive Officer since July 2009. From January 2006 to December 2007, Mr. Raykov was a portfolio manager for Alchem Investment Partners and John Levin & Co. Prior to founding Alchem, Mr. Raykov was a portfolio manager and securities analyst for John A. Levin & Co. Event Driven Fund (2002-2005). Prior to joining John A. Levin & Co., Mr. Raykov was a securities analyst for the Merger Fund at Tiedemann Investment Group (1999-2002) and an investment banking analyst at Bear Stearns (1998-1999). Mr. Raykov earned a B.S. in Business Administration from the University of North Carolina at Chapel Hill. As a result of these and other professional experiences, Mr. Raykov has financial expertise and experience with the Corporation as it has developed within the drug development industry and, as such, is able to provide the Corporation with unique insight and guidance.

Robert Andrade

Mr. Andrade has served as Chief Financial Officer since November 2015. Mr. Andrade was previously Chief Financial Officer and Director of Fennec from September 2009 until August 2013. In addition to his role with Fennec, Mr. Andrade was a private investor in 2015, and a senior analyst at Magnetar Capital from 2013 - 2014. Mr. Andrade graduated from University of Southern California, where he earned a Masters of Arts degree and Bachelor of Arts degree in economics.

Chris A. Rallis

Mr. Rallis has served as a director of Fennec since August 2011. Mr. Rallis has been an executive-in-residence at Pappas Capital, a life science venture capital firm since January 2008. Previously, Mr. Rallis was the President and Chief Executive Officer of ImmunoBiosciences, Inc. ("IBI"), a vaccine technology company formerly located in Raleigh, North Carolina from April 2006 through June 2007. Prior to joining IBI, Mr. Rallis served as an executive-in-residence (part-time) for Pappas Capital, and as a consultant for Duke University and Panacos Pharmaceuticals, Inc. Mr. Rallis is the former President and Chief Operating Officer ("COO") and director of Triangle Pharmaceuticals, Inc., which was acquired by Gilead Sciences in January 2003 for approximately $465 million. Prior to assuming the role of President and COO in March 2000, he was Executive Vice President, Business Development and General Counsel. While at Triangle, Mr. Rallis participated in 11 equity financings generating gross proceeds of approximately $500 million. He was also primarily responsible for all business development activities which included a worldwide alliance with Abbott Laboratories and the in-licensing of ten compounds. Before joining Triangle in 1995, Mr. Rallis served in various business development and legal management roles with Burroughs Wellcome Co. over a 13-year period, including Vice President of Strategic Planning and Business Development. Mr. Rallis also serves on the board of Lung Cancer Initiative of NC, located in Raleigh, North Carolina. Mr. Rallis received his A.B. degree in economics from Harvard College and a J.D. from Duke University. As a result of these and other professional experiences, Mr. Rallis possesses particular healthcare industry knowledge and experience which strengthens the Board's collective qualifications, skills, and experience.

Dr. Marco Brughera

Dr. Brughera has been a director of Fennec since August 2016. Currently, he is the founder at Brucon srls and Strategic Advisor at Essetifin. From 2011 until 2021, Dr. Brughera had been CEO of Lediant Biosciences and has held several positions for the Sigma-Tau Group, including CEO and Global Head of Sigma Tau Rare Disease, President of Sigma-Tau Research and President of Sigma-Tau Pharmaceuticals. He drove the commercial revival of a lead oncology product line resulting in its successful sale for a total of around $900M. He also successfully out-licensed the Defibrotide US rights to Jazz Pharmaceuticals. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Sciences (NMS), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, an independent contract research organization with the NMS Group. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of research and development with Pharmacia and Pfizer. Prior to 1999, he held various positions at Pharmacia & Upjohn and Farmitalia Carlo Erba SpA, an Italian pharmaceutical company. He currently serves on the Board of Leadiant Biosciences Inc and Limited; advisor and biotech champion at Indaco Ventures Partners SGR. Previously was a Board member of Gentium, Exelead, Soligenix, Lee's Pharmaceuticals and Naicons.

Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist. Dr. Brughera has wide-spread experience and knowledge of pharmaceutical drug development in international companies. His knowledge in particular, of clinical drug development in Europe, deepens the Board's collective qualifications, skills and experience.

Adrian J. Haigh

Mr. Haigh has been a director of Fennec since April 2014. Mr. Haigh retired from PTC Therapeutics on Dec 31st 2022, his last role at PTC was Senior Vice President and Head of International, he joined the company in 2014 as Head of EMEA and built the company's international organization. Previously Mr. Haigh served as Chief Operating Officer at Gentium GmbH since March 2011. Prior to joining Gentium, Mr. Haigh served as Regional VP Commercial Operations at Biogen Idec where he managed several affiliates and also the global distributor business and prior to that was the General Manager of Amgen Nordic and Portugal. He served as the Executive Vice President of Global Marketing and Corporate Planning at EUSA Pharma and joined EUSA from Amgen where he led the international oncology franchise. Mr. Haigh previously has held senior commercial and marketing positions at SmithKline Beecham, Schering Plough, Organon and Novo Nordisk. He has been a Director of Fennec Pharmaceuticals Inc. since April 28, 2014. He received a Bachelor of Arts with Honors in Economic History from Huddersfield Polytechnic, West Yorkshire, England, a Diploma in Marketing from the Institute of Marketing and a Diploma in Company Direction from the Institute od Directors. As a result of these and other professional experiences, Mr. Haigh has extensive international oncology development expertise which strengthens the Board's collective qualifications, skills and experience.

Dr. Khalid Islam

Dr. Islam has been a director of Fennec since April 2014 and is our current Chairman of the Board. Dr. Islam was the Chairman and CEO of Gentium S.p.A. (a Nasdaq-listed company; 2009-2014) where he led the transition from a loss-making to a cash-flow positive and profitable company. Under his leadership, the company value increased from US$25 million leading to a successful all cash US$1 billion merger with Jazz Pharmaceuticals, plc. Subsequent to the sale of Gentium, Dr. Islam has been involved from both an advisory and board level in several public and private healthcare related companies. From 1999-2008, Dr. Islam was President and CEO of Arpida AG where he transitioned the early-stage start-up to a SWX-listed company and raised US$300 million in the IPO and follow-ons. From 1987-1999, he held various positions in HMR & MMD (now Sanofi-Aventis). From 1977-1987, Dr. Islam worked in academia at Imperial College (Univ. of London) and in Milan University, where he was a contract professor. Dr. Islam is a graduate of Chelsea College and received his Ph.D. from Imperial College, University of London. He holds several patents and has published over 80 articles in leading journals. He is an advisor to the venture group Kurma Biofund (Paris). He is a founder/co-founder of Gain Therapeutics Inc. (GANX), Sirius Healthcare Partners GmbH (Zurich), PrevAbr LLC (D.C.), BioAim LLC (L.A.) & Life Sciences Management GmbH (Zug). Dr. Islam is Board Chair at Minoryx Therapeutics (Spain) and Gain Therapeutics Inc. (GANX), a public company. . In the past, he has served on the Board of Directors of Immunomedics (USA), Processa Pahramacueticals (PCSA), Pcovery Aps (Denmark), Adenium Aps (Denmark), C10 Pharma AS (Norway), Karolinska Development (KDEV, Sweden) and MolMed S.p.A. (MLMI, Italy). Dr. Islam's extensive international pharmaceutical expertise in transitioning companies from development to production strengthens the Board's collective qualifications, skills and experience.

Dr. Jodi Cook

Dr. Cook has been a director of Fennec since September 2019. Dr. Cook is currently CEO of Skylark Bio Inc, an early-stage Company working on gene therapy for genetic disorders. Dr. Cook previously served as SVP and Head of Gene Therapy Strategy at PTC Therapeutics from August 2018 until February 2020. Previously she was one of the founding members and Chief Operating Officer of Agilis Biotherapeutics, a clinical-stage company focused on gene therapies for rare diseases of the central nervous system, from December 2013 until its acquisition by PTC Therapeutics in August 2018. While at Agilis she led the sale of the company to PTC in a deal that represented significant value to all parties. Dr. Cook's career spans a wide range of experiences including VP of Clinical Research at InSound Medical and Director of Audiology at Songbird Hearing, both successful biotech start-up companies within the hearing industry. She has been Assistant Professor of Audiology and Director of the Hearing Aid Program at Mayo Clinic. Dr. Cook earned a BA from Loyola University in Maryland, M.Aud. from University of South Carolina, and PhD from Arizona State University in Hearing Science. She completed a clinical fellowship at Johns Hopkins School of Medicine in Baltimore, MD. Her extensive scientific, clinical and executive business experience strengthens the Board's collective qualifications, skills and expertise.

Audit Committee

On behalf of the Board, the Audit Committee of the Board retains, oversees and evaluates our independent auditors, reviews the financial reports and other financial information provided by us, including audited financial statements, and discusses the adequacy of disclosure with management and the auditors. The Audit Committee also reviews the performance of the independent auditors in the annual audit and in assignments unrelated to the audit, assesses the independence of the auditors, and reviews their fees. The Audit Committee is also responsible for reviewing our internal controls over financial reporting and disclosure. The Audit Committee operates under a written charter adopted by the Board.

The directors have appointed an Audit Committee consisting of three directors: Chris A. Rallis, Khalid Islam and Adrian Haigh, each of whom is independent and financially literate within the meaning of National Instrument 52-110 – Audit Committees and is independent under Rule 5605(a)(2) of the Nasdaq listing standards. In addition, the Board has determined that Mr. Rallis qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC based on his business and financial experience described above.

Code of Ethics

In February 2004, our Board adopted a Mandate of the Board of Directors, Corporate Governance Guidelines and a Code of Business Conduct and Ethics (the "Conduct and Ethics Code") applicable to all of our officers, directors and

employees. We are committed to adhering to applicable legal requirements and maintaining the highest standards of conduct and integrity. The Conduct and Ethics Code sets out the legal and ethical standards of conduct for our personnel and addresses topics such as: reporting obligations and procedures; honest and ethical conduct and conflicts of interest; compliance with applicable laws and Company policies and procedures; confidentiality of corporate information; use of corporate assets and opportunities; public disclosure and books and records; and non-retaliation. The Conduct and Ethics Code was updated in June of 2019 and is available on our website at www.fennecpharma.com.

We will post any amendment to this code, as well as any waivers that are required to be disclosed by the rules of the SEC, on our website promptly following the date of such amendment or waiver. We undertake to provide to any person without charge, upon request, a copy of the Conduct and Ethics Code by writing to Attn: Code of Ethics Request, Fennec Pharmaceuticals Inc., 68 TW Alexander Drive, PO Box 13628, Research Triangle Park, North Carolina 27709.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets out certain information respecting the compensation paid to our Chief Executive Officer, our Chief Financial Officer, and our former Chief Commercial Officer ("Named Executive Officers") for the fiscal years ended December 31, 2022 and December 31, 2021.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Restricted Share Unit Awards ($)[2]	Option Awards ($)[1]	Total ($)
Rostislav Raykov, CEO	2022	503,436	110,725	—	—	614,161
	2021	468,452	—	—	2,951,923	3,420,375
Robert Andrade, CFO	2022	364,698	64,221	—	—	428,919
	2021	339,409	—	153,000	1,006,364	1,498,773
Shubh Goel, CCO	2022	8,637	—	—	—	8,637
	2021	376,505	—	153,000	1,006,364	1,535,869

(1) Represents the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Dollar value amounts are based on individual grants to each of Mr. Raykov, Mr. Andrade and Ms. Goel of 300,000, 250,000 and 75,000, 100,000 and 75,000, 100,000 options, respectively, on December 20, 2021 and June 2, 2021, at an exercise price of $4.08 and $7.53 per common share, respectively. On December 20, 2021, Mr. Andrade and Ms. Goel were also awarded 37,500 Restricted Share Units each. The December 20, 2021 awards and grants to the executives all vested conditionally upon FDA approval of PEDMARK® in calendar year 2022 with executive still employed at the Company. All option grants expire 10 years after grant date. The June, 2021 grants vest in the following manner: one-third of these options shall vest and may be exercised one year after the grant date (the "Vesting Commencement Date"). The remaining two-thirds of the options shall vest monthly at a rate of 1/24th of the remaining grant and shall be exercisable as of the last day of each following month after the Vesting Commencement Date. As of the third anniversary of the grant date, all of the options shall be vested.

Rostislav Raykov

Mr. Raykov has been employed by us since July 2009. Pursuant to an employment agreement dated May 3, 2010 between Mr. Raykov and Fennec, Mr. Raykov is employed as our Chief Executive Officer and: (a) received an initial annual salary in the amount of $140,000, subject to annual adjustment by our Board of Directors, (b) upon approval by shareholders of our amended stock option plan was granted options to purchase up to 5.0% of our common shares estimated by us to be outstanding upon completion of our 2010 rights offering, and (c) may receive annual bonuses at the sole discretion of the Board. If Mr. Raykov's employment terminates due to a change of control of Fennec, Mr. Raykov's remaining unvested options shall immediately vest and be fully exercisable. If Mr. Raykov is dismissed from employment by us for any reason other than "for cause," we are obligated to pay Mr. Raykov severance compensation equal to twelve months of salary. The initial term of the agreement was for one year and the agreement automatically extends for additional one-year periods unless terminated by either party in accordance with the agreement. Effective December 31, 2022, Mr. Raykov's salary is $513,400 per year.

Robert Andrade

Mr. Andrade has been employed by us since November 2015. Pursuant to an employment agreement dated November 13, 2015, Mr. Andrade is employed as our Chief Financial Officer and: (a) received an initial annual salary in the amount of $165,000, and (b) may receive annual bonuses at the sole discretion of the Board. If Mr. Andrade's employment terminates due to a change of control of the Fennec, Mr. Andrade's remaining unvested options shall immediately vest and be fully exercisable. If Mr. Andrade is dismissed from employment by us for any reason other than "for cause," we are obligated to pay Mr. Andrade severance compensation equal to six months of salary. Effective December 31, 2022, Mr. Andrade's salary is $371,914 per year.

Shubh Goel

Ms. Goel commenced employment with us in September 2019. Pursuant to an employment agreement dated September 9, 2019, Ms. Goel was employed as our Chief Commercial Officer and: (a) received an initial annual salary in the amount of $360,000, subject to annual adjustment by our Board of Directors, and (b) was eligible to receive an annual bonus of up to 40% of her base salary per twelve month period, at the discretion of the CEO and the Board of Directors. If Ms. Goel's employment was terminated by us for any reason other than "for cause", we would have been obligated to pay Ms. Goel (i) severance in the amount of six months of employees base salary, (ii) prorated share of any target bonus earned by Ms. Goel and, (iii) accelerated vesting of stock options. The initial term of the agreement was for one year and the agreement automatically extended for additional one-year periods unless terminated by either party in accordance with the agreement. Ms. Goel tendered her resignation on January 31, 2022.

In addition to their employment agreements, Mr. Raykov, Mr. Andrade and Ms. Goel are a party to a confidentiality and intellectual property agreement with the Company.

In the employment agreements for each of Mr. Raykov, Mr. Andrade and Ms. Goel, "for cause" is generally defined as (1) material breach of the terms of the employment or intellectual property agreements; (2) failure to perform the duties inherent in their position in good faith and in a reasonable and appropriate manner; or (3) acts of fraud or embezzlement or other intentional misconduct which adversely affects our business.

Payments on Termination

The following table provides details regarding the estimated incremental payments from us to each of the Named Executive Officers assuming termination without cause on December 31, 2022. Ms. Goel's resignation was voluntary and there is no severance owed.

Name	Severance	Estimated Bonus	Value of benefits
Rostislav Raykov, CEO	$ 468,452	$ 256,705	$ 725,157
Robert Andrade, CFO	$ 169,705	$ 153,511	$ 323,216
Shubh Goel, CCO	$ 94,126	$ —	$ 94,126

Payments on Change of Control

The following table provides details regarding the estimated incremental payments from us to each of the Named Executive Officers upon change of control.

Name	Change of Control Multiple	Estimated Bonus[1]	Value of benefits
Rostislav Raykov, CEO	2 X	$ 1,213,005	$ 1,213,005
Robert Andrade, CFO	1.25 X	$ 528,919	$ 528,919

(1) Change of control payments are calculated based on the two-year annualized average salary plus cash bonus as calculated as of December 31, 2022.

In addition to the payments above, an incentive plan has been established pursuant to which, upon completion of a change in control transaction prior to December 31, 2023, 1% of the transaction value up to $350 million and 1.25% of the transaction value in excess of $350 million up to $400 million and 1.5% of transaction value in excess of $400 million,

with 50% of such incentive pool being payable to the CEO, 30% to the CFO and the balance to other key personnel as determined by the CEO in consultation with the Compensation Committee.

Equity Grants, Exercises and Holdings

The following table sets forth information concerning the number and value of unexercised options held by each Named Executive Officer as of December 31, 2022. All executive awards, with the exception of those expiring 05/15/2030 and 06/02/2031, are exercisable immediately. Grants expiring 12/20/2031 fully vested upon FDA approval of PEDMARK®. Our current stock option plan provides for equity awards and grants denominated in US and CAD dollars.

	Number of Options				
Name	Granted	Exercisable	Option Exercise Price		Expiration Date
Rostislav Raykov	300,000	300,000	USD$	4.08	12/20/2031
	250,000	131,948	USD$	7.53	06/02/2031
	250,000	222,224	USD$	6.93	05/15/2030
	150,000	150,000	USD$	4.83	04/04/2029
	100,000	100000	USD$	8.38	02/06/2028
	100,000	100000	USD$	5.10	06/27/2027
	150,000	150,000	USD$	2.45	07/05/2026
	25,000	25,000	USD$	2.69	12/31/2024
	83,333	83,333	USD$	1.59	01/24/2024
	16,666	—	USD$	0.72	08/23/2023
	50,000	—	USD$	1.05	11/20/2022
Robert Andrade	75,000	75,000	USD$	4.08	12/20/2031
	100,000	52,779	USD$	7.53	06/02/2031
	125,000	111,112	USD$	6.93	05/15/2030
	80,000	80,000	USD$	4.83	04/04/2029
	50,000	50,000	USD$	8.38	02/06/2028
	50,000	50,000	USD$	5.10	06/27/2027
	75,000	75,000	USD$	2.45	07/05/2026

Compensation of Directors

Director Compensation Table

The following table summarizes the compensation earned by our non-executive directors for the year ended December 31, 2022.

Name	Fees paid in Cash	Stock Awards	Option Awards[1][2]	Total
Dr. Islam	85,000	—	83,692	168,692
Mr. Brughera	40,000	—	66,952	106,952
Mr. Haigh	40,000	—	66,952	106,952
Dr. Cook	35,000	—	66,952	101,952
Mr. Rallis	42,500	—	66,952	109,452
Total	**$ 242,500**	**$ —**	**$ 351,500**	**$ 594,000**

(1) Represents the aggregate grant date fair value computed in accordance with FASB ASC Topic 718.
(2) Detail of option grants are presented in the following table:

Name	Date of Grant	Number of Options Granted	Option Exercise Price $USD
Mr. Rallis	June 14, 2022	20,000	5.59
Mr. Brughera	June 14, 2022	20,000	5.59
Mr. Haigh	June 14, 2022	20,000	5.59
Dr. Islam	June 14, 2022	25,000	5.59
Dr. Cook	June 14, 2022	20,000	5.59
Total		**105,000**	

The annual compensation considerations for non-executive directors also include the awarding of stock options. We believe that granting of options to the non-executive directors serves three primary purposes: (1) to recognize the significant time and effort commitments of being a member of our Board; (2) to provide long-term incentives for future efforts since the value of the options is directly dependent on our market valuation; and (3) to retain quality individuals. When determining whether and how many new option grants will be made, the Compensation Committee takes into account the amount and terms of any outstanding options. We do not require our non-executive directors to own a specific amount of our common shares.

Each of Adrian J. Haigh, Khalid Islam, Marco Brughera, Jodi Cook and Chris A. Rallis has entered into an Independent Director Agreement with the Company, which provides for cash compensation as set forth by the Compensation Committee commensurate with that member's responsibilities. The Compensation Committee may also remunerate members in the form of a grant of options to purchase shares of our common shares. The options immediately vest when granted and are otherwise subject to the terms and conditions of our stock option plan, as amended. The Independent Director Agreements also provide for the reimbursement of such director's reasonable travel and related expenses incurred in the course of attending board meetings.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information regarding our common shares beneficially owned as of March 27, 2023 by: (i) each of our officers and directors; (ii) all officers and directors as a group; and (iii) each person known by us to beneficially own five percent or more of our outstanding common shares. Except as indicated below, the security holders listed possess sole voting and investment power with respect to the shares beneficially owned by that person. Except as otherwise indicated below, the address for each listed shareholder is c/o Fennec Pharmaceuticals Inc., 68 TW Alexander Drive, PO Box 13628, Research Triangle Park, North Carolina 27709.

Name	Common shares	Common shares Options Exercisable Within 60 Days	Common shares Purchase Warrants Exercisable Within 60 Days	Total Stock and Stock Based Holdings[1]	% Ownership[1]
Adrian J. Haigh	—	273,579	—	273,579	1.03 %
Dr. Khalid Islam	—	363,825	—	363,825	1.36 %
Robert Andrade	149,721	518,891	—	668,612	2.48 %
Marco Brughera	—	155,545	—	155,545	0.59 %
Jodi Cook	—	80,000	—	80,000	0.30 %
Chris A. Rallis	32,077	189,186	—	221,263	0.83 %
Rostislav Raykov	217,838	1,318,061	—	1,535,899	5.54 %
All Officers and Directors as a Group	**399,636**	**2,899,087**	**—**	**3,298,723**	**10.97 %**
Southpoint Capital Advisors, LP.[2]	4,077,214	—	—	4,077,214	15.44 %
Essetifin SpA[3]	3,993,694	—	—	3,993,694	15.12 %
Sonic Fund II, LP.[4]	2,578,134	—	—	2,495,753	9.77 %
Avaro	1,670,000	—	—	1,670,000	6.32 %

(1) For purposes of this table "beneficial ownership" is determined in accordance with Rule 13d-3 under the Exchange Act, pursuant to which a person or group of persons is deemed to have "beneficial ownership" of any common shares that such person or group has the right to acquire within 60 days after March 27, 2023. For purposes of computing the percentage of outstanding common shares held by each person or group of persons named above, any shares that such person or group has the right to acquire within 60 days after March 27, 2023 are deemed outstanding but are not deemed to be outstanding for purposes of computing the percentage ownership of any other person or group. As of March 27, 2023 there were 26,411,520 common shares issued and outstanding.

(2) Southpoint Capital Advisors, LP, 623 Fifth Avenue, Suite 2503, New York, New York 10022. John S. Clark, II holds voting and investment power over the shares owned by Southpoint Capital Advisors, LP.

(3) Essetifin SpA, Via Sudafrica 20, Rome, Italy 00144. Mario Artali holds voting and investment power over the shares owned by Essetifin SpA.

(4) Sonic Fund II, LP, 400 Hobron Lane, Suite 3709, Honolulu, HI 96815. Lawrence Kam holds voting and investment power over the shares held by Sonic Fund II, LP.

(5) Avaro Capital Advisors, LLC, 110 Greene Street, Suite 800, New York, NY 10012. Scott Epstein holds voting and investment power over the shares owned by Avoro Capital Advisors, LLC.

Equity Compensation Plan Information

The following table provides certain information with respect to securities authorized for issuance under equity incentive plans as of December 31, 2022.

(share amounts are in thousands):

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column (a))
Equity compensation plans approved by security holders	4,689	USD $5.51	2,062
Total	**4,689**	—	**2,062**

* Our current stock option plan allows for the issuance of equity awards and grants denominated in both U.S. dollars and Canadian dollars. At December 31, 2022, there were 2.2 million common shares available for future grants under our current stock option plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Party Transactions

There were no reportable transactions with related parties during the year ended December 31, 2022 in which the amount involved exceeded the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years.

Indemnifications Related to Officers and the Board of Directors.

We have agreed to indemnify members of our Board of Directors (the "Board") and certain of our officers if they are named or threatened to be named as a party to any proceeding by reason of the fact that they acted in such capacity. We maintain directors' and officers' ("D&O") insurance coverage to protect against such losses. We have not historically incurred any losses related to these types of indemnifications. Presently, we are defending a suit against our Board and certain named officers. Management is unable to estimate a dollar value related to the suit, nor can it determine the probability of an outcome either in favour or against the Company. As a result, we have not recorded any liabilities related to such indemnifications as of December 31, 2022. In addition, as a result of D&O insurance policy coverage, we believe these indemnification agreements are not significant to our results of operations.

Director Independence

The Board of Directors is composed of a majority of independent directors. The Board applies the definition of independence found in the Nasdaq listing standards and in Canadian National Instruments 52-110 and 58-101 and National Policy 58-201. The Board has determined that Mr. Brughera, Haigh, Islam, Rallis and Ms. Cook are "independent." Mr. Raykov, our Chief Executive Officer, is considered to have a material relationship with us by virtue of his executive officer position and is therefore not independent. We are of the view that the composition of our Board reflects a diversity of background and experience that are important for effective corporate governance. Other directorships held by Board members are described in this Annual Report under the heading "Directors and Executive Officers."

Item 14. Principal Accounting Fees and Services

The following presents the aggregate fees for professional services and other services rendered by our independent auditors, Haskell & White LLP (PCAOB ID# 200), in fiscal year 2022 and 2021:

	Fiscal Year 2022	Fiscal Year 2021
Audit Fees[1]	$ 86,250	$ 73,100
Audit-Related Fees[2]	7,500	15,500
Tax Fees[3]	—	—
All Other Fees[4]	—	—
Total	**$ 93,750**	**$ 88,600**

(1) *Audit Fees* include fees for the standard audit work that needs to be performed each year in order to issue an opinion on the consolidated financial statements of the Company. It also includes fees for services that can only be provided by the Company's auditor such as auditing of non-recurring transactions.
(2) *Audit-Related Fees* include fees assurance and related services that are reasonably related to the performance of the audit or review and are traditionally performed by the independent accountant.
(3) *Tax Fees*
(4) *All Other Fees* include fees for products and services other than Audit Fees, Audit Related Fees and Tax Fees.

The Audit Committee does not have formal pre-approval policies and procedures; however, prior to their engagement by us, the Audit Committee approved all of the services performed by Haskell & White LLP as required by SEC regulation.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are included as part of this Annual Report:

1. Financial Statements – See Index to Financial Statements on page F-1.
2. All schedules are omitted as the information required is inapplicable or the information is presented in the financial statements.
3. Exhibits:

Exhibit No.	Description	Location
3.1	Notice of Articles dated August 25, 2011	Exhibit 3.2I to the Form 8-K of the Company filed August 26, 2011
3.2	Articles dated August 25, 2011	Exhibit 3.2II to the Form 8-K of the Company filed August 26, 2011
3.3	Notice of Alteration Dated September 3, 2014	Exhibit 3.1 to the Form 8-K of the Company filed September 9, 2014
10.1	Fennec Amended and Restated Stock Option Plan*	Exhibit 10.1 to the Form 8-K of the Company filed September 29, 2017
10.2	Executive Employment Agreement dated May 3, 2010 by and between Fennec and Rostislav Raykov*	Exhibit 10.28 to the Form 10-Q of the Company filed May 14, 2010
10.3	Form of Independent Director Agreement, dated May 3, 2010	Exhibit 10.31 to the Form 10-Q of the Company filed May 14, 2010
10.4	Executive Employment Agreement dated November 12, 2015 by and between Fennec and Robert Andrade*	Exhibit 10.40 to the Form 10-Q of the Company filed November 12, 2015
10.5	Purchase Agreement, dated May 9, 2016, between Fennec Pharmaceuticals Inc. and Elion Oncology, LLC.	Exhibit 10.42 to the Form 10-Q of the Company filed May 12, 2016
10.6	Loan and Security Agreement dated as of February 1, 2019 by and between Fennec Pharmaceuticals, Inc. and Western Alliance Bank	Exhibit 10.1 to the Form 8-K of the Company filed February 4, 2019
10.7	First Amendment to Loan and Security Agreement dated as of June 25, 2020 by and between Fennec Pharmaceuticals, Inc. and Western Alliance Bank	Exhibit 10.1 to the Form 8-K of the Company filed June 26, 2020
10.8	Second Amendment to Loan and Security Agreement dated as of June 24, 2021 by and between Fennec Pharmaceuticals, Inc and Western Alliance Bank	Exhibit 10.1 to the form 8-K of the Company filed June 24, 2021
10.9	Third Amendment to Loan and Security Agreement dated as of January 27, 2022 by and between Fennec Pharmaceuticals, Inc and Western Alliance Bank	Exhibit 10.1 to the form 8-K of the Company filed January 31, 2022
10.10	At The Market Offering Agreement, dated October 30, 2020, between Fennec Pharmaceuticals Inc. and H.C. Wainwright & Co., LLC	Exhibit 1.1 to the Form 8-K of the Company filed October 30, 2020
10.11	Executive Employment Agreement of Shubh Goel	Exhibit 10.1 to the form 8-K of the Company filed September 9, 2019
10.12	First Closing of Financing Transaction, dated August 22, 2022, by and between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 4.1 to the form 8-K of the Company filed August 22, 2022
10.13	Second Closing of Financing Transaction, dated September 23, 2022, by and between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 4.1 to the form 8-K of the Company filed September 26, 2022

Exhibit No.	Description	Location
10.14	Share Registration Agreement, dated as of December 1, 2022, between Fennec Pharmaceuticals, Inc. and Petrichor Opportunities Fund I LP	Exhibit 4.5 to the Form S-3 of the Company filed December 1, 2022
16.1	Letter Regarding Change in Certifying Accountant	Exhibit 16.1 to the Form 8-K of the Company filed May 17, 2017
21	Subsidiaries	Exhibit 21 to the 10-K of the Company filed February 14, 2020
23.1	Consent of Haskell & White LLP, Independent Registered Public Accounting Firm	Filed herewith

Exhibit No.	Description	Location
31.1	Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Chief Executive Officer and Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
99.1	Press Release for Fiscal Year Ended December 31, 2022	Filed herewith
101.1	Interactive Data File	Filed herewith
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	Filed herewith

* Indicates a management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 of 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Fennec Pharmaceuticals Inc.

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

Date: March 29, 2023

We, the undersigned directors and officers of Fennec Pharmaceuticals Inc., do hereby constitute and appoint Rostislav Raykov, as our true and lawful attorney-in-fact and agent with power of substitution, to do any and all acts and things in our name and behalf in our capacities as directors and officers and to execute any and all instruments for us and in our names in the capacities indicated below, which such attorney-in-fact and agent may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission, in connection with this Annual Report on Form 10-K, including specifically but without limitation, power and authority to sign for us or any of us in our names in the capacities indicated below, any and all amendments hereto; and we do hereby ratify and confirm all that said attorney-in-fact and agent, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Rostislav Raykov **Rostislav Raykov**	Chief Executive Officer (principal executive officer) and Director	March 29, 2023
/s/ Robert Andrade **Robert Andrade**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 29, 2023
/s/ Adrian J. Haigh **Adrian J. Haigh**	Director	March 29, 2023
/s/ Dr. Khalid Islam **Dr. Khalid Islam**	Director	March 29, 2023
/s/ Chris A. Rallis **Chris A. Rallis**	Director	March 29, 2023
/s/ Marco Brughera **Marco Brughera**	Director	March 29, 2023
/s/ Jodi Cook **Jodi Cook**	Director	March 29, 2023

FENNEC PHARMACEUTICALS INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
Fennec Pharmaceuticals Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Fennec Pharmaceuticals Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, shareholders' (deficit) equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and Canadian generally accepted auditing standards. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (Continued)

Estimated Product Discounts and Allowances

Critical Audit Matter Description

As discussed in Note 2 to the consolidated financial statements, the Company recognizes revenues at the net sales price, which includes estimates of variable consideration for which reserves are established primarily from rebates, chargebacks, discounts, returns and other allowances (the "allowances"). The estimation of these allowances is an important factor in the determination of net sales price and requires subjective management assumptions. Allowances totaled approximately $234,000 for the year ended December 31, 2022, and such amounts were recorded as reductions to trade receivables or accrued expenses as of December 31, 2022, depending on the nature of the contract and the related settlement.

How the Critical Audit Matter was Addressed in the Audit

Auditing the Company's estimated allowances was complex and judgmental because the estimates involve subjective management assumptions about the product's end users at the time of product distribution. Reductions to gross product revenue are sensitive to changes in management's assumptions. Furthermore, PEDMARK® is the Company's first commercial product, and as a result, management does not have Company-specific historical experience to make those estimates and relies on industry data and any known trends in making those estimates.

To test the allowances, our audit procedures included, among others:

- Through inquiry and observation, we obtained an understanding of the significant management assumptions supporting each potentially significant component of the allowances, including the nature of each allowance and the related percentage estimated by management.
- We assessed the methodologies used to determine the allowances and tested estimated percentages by corroborating the underlying data used to develop the estimate, which included the completeness and accuracy of such data. Our testing included comparing key assumptions used to calculate the allowances to external data, customer contracts, and payment data.
- We evaluated information subsequent to the balance sheet date to determine whether there was any new information that would require adjustment to the previously recorded allowances.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2017.

Irvine, California
March 29, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 23,774	$ 21,100
Accounts receivable, net	1,545	—
Prepaid expenses	770	1,034
Inventory	576	—
Other current assets	63	253
Total current assets	26,728	22,387
Non-current assets		
Deferred issuance cost, net of amortization	211	27
Total non-current assets	211	27
Total assets	$ 26,939	$ 22,414
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,390	$ 777
Accrued liabilities	2,219	877
Total current liabilities	4,609	1,654
Long term liabilities		
Term loan	25,000	5,000
PIK interest	260	—
Debt discount	(361)	(12)
Total long term liabilities	24,899	4,988
Total liabilities	29,508	6,642
Commitments and Contingencies (Note 7)		
Shareholders' (deficit) equity:		
Common stock, no par value; unlimited shares authorized; 26,361 shares issued and outstanding (2021 -26,014)	142,591	140,801
Additional paid-in capital	56,797	53,214
Accumulated deficit	(203,200)	(179,486)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(2,569)	15,772
Total liabilities and shareholders' (deficit) equity	$ 26,939	$ 22,414

(The accompanying notes are an integral part of these consolidated financial statements)

Fennec Pharmaceuticals Inc.
Consolidated Statements of Operations
(U.S. dollars and shares in thousands, except per share information)

	Year Ended	
	December 31, 2022	December 31, 2021
Revenue		
PEDMARK product sales, net	$ 1,535	$ —
Cost of products sold	(86)	—
Gross profit	1,449	—
Operating expenses:		
Research and development	3,531	4,981
Selling and marketing	2,785	—
General and administrative	17,722	12,242
Total operating expenses	24,038	17,223
Loss from operations	(22,589)	(17,223)
Other (expense)/income		
Unrealized foreign exchange loss	(9)	(10)
Amortization expense	(149)	(16)
Unrealized loss on securities	(184)	(25)
Interest income	195	54
Interest expense	(978)	(126)
Total other (expense)/income	(1,125)	(123)
Net loss	$ (23,714)	$ (17,346)
Basic net loss per common share	$ (0.90)	$ (0.67)
Diluted net loss per common share	$ (0.90)	$ (0.67)
Weighted-average number of common shares outstanding basic	26,275	26,006
Weighted-average number of common shares outstanding diluted	26,275	26,006

(The accompanying notes are an integral part of these consolidated financial statements)

Fennec Pharmaceuticals Inc.
Consolidated Statements of Shareholders' (Deficit) Equity
(U.S. dollars and shares in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' (Deficit) Equity
	Number (Note 6)	Amount				
Balance at December 31, 2020	**26,003**	**$ 140,733**	**$ 49,234**	**$ (162,140)**	**$ 1,243**	**$ 29,070**
Stock options issued to consultants	—	—	266	—	—	266
Stock options issued to employees	—	—	3,749	—	—	3,749
Exercise of stock options	11	68	(35)	—	—	33
Net loss	—	—	—	(17,346)	—	(17,346)
Balance at December 31, 2021	**26,014**	**140,801**	**53,214**	**(179,486)**	**1,243**	**15,772**
Stock options issued to consultants	—	—	133	—	—	133
Stock options issued to employees	—	—	4,087	—	—	4,087
Warrants issued in connection with term loan	—	—	441	—	—	441
Exercise of stock options	273	1,790	(862)	—	—	928
Restricted stock release	74	—	(216)	—	—	(216)
Net loss	—	—	—	(23,714)	—	(23,714)
Balance at December 31, 2022	**26,361**	**$ 142,591**	**$ 56,797**	**$ (203,200)**	**$ 1,243**	**$ (2,569)**

(The accompanying notes are an integral part of these consolidated financial statements)

Fennec Pharmaceuticals Inc.
Consolidated Statements of Cash Flows
(U.S. dollars in thousands)

	Year Ended	
	December 31, 2022	December 31, 2021
Cash flows (used in) provided by:		
Operating activities:		
Net loss	$ (23,714)	$ (17,346)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt access fees	132	14
Amortization of debt discount	17	2
Unrealized loss on securities	184	25
Stock-based compensation - consultants	133	266
Stock-based compensation - employees	4,087	3,749
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,545)	—
Prepaid expenses	264	(237)
Inventory	(576)	—
Other assets	6	(2)
Accounts payable	1,612	(794)
Accrued liabilities	1,342	101
Net cash used in operating activities	(18,058)	(14,222)
Financing activities:		
Issuance of shares, options exercise	928	33
Proceeds from long-term debt	24,935	5,000
Long term debt paid	(5,000)	—
Debt discount	238	(14)
Cash paid for taxes on restricted share release	(194)	—
Capitalized deferred issuance costs	(175)	(41)
Net cash provided by financing activities	20,732	4,978
Increase/(decrease) in cash and cash equivalents	2,674	(9,244)
Cash and cash equivalents - Beginning of year	21,100	30,344
Cash and cash equivalents - End of year	$ 23,774	$ 21,100
Non-cash investing and financing activities:		
Financed insurance policy	$ 550	$ 466
Warrants issued in connection with term loan	$ 441	$ —

(The accompanying notes are an integral part of these 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 ("Fennec Limited"), collectively referred to herein as the "Company," is a biopharmaceutical company with one FDA approved product developed to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

These 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 year ended December 31, 2022, the Company incurred a net loss from operations of $23,714. At December 31, 2022, it had an accumulated deficit of $203,200 and had experienced negative cash flows from operating activities in the amount of $18,058 for the year ended December 31, 2022.

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 Securities Purchase Agreement ("SPA") dated August 1, 2022. In connection with the first closing, the Company repaid in full its secured indebtedness with Bridge Bank in the amount of $5,000.

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

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. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 Fennec common shares ("First Closing Warrant") and half was payable in cash or warrants of 55,498 Fennec common shares ("Second Closing Warrant"), at our election, on the second closing. The warrants are exercisable at a price per share of $8.11 and will have a term of five years from the date of the grant. The Company elected to have all the commitment fee of the Notes payable in warrants.

The Company believes current funds, which include funds from the First Closing Note and the Second Closing Note, provide sufficient funding for the Company to carry out its planned activities, including the continuation of commercialization efforts for at least the next twelve months of PEDMARK®.

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

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Fennec and of all its wholly-owned subsidiaries. All inter-company transactions and balances have been eliminated upon consolidation.

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 December 31, 2022 and 2021, the Company has no net assets 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 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.

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. The Company sells its products principally through the following specialty distributors: Amerisource Specialty Distribution ("ASD"), McKesson Plasma and Biologics, McKesson Specialty and Cardinal Health Specialty (collectively the "Customers" and each a "Customer"). These Customers 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 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, general and administrative expenses in its Consolidated Statements of Operations.

The following table summarizes net product revenues for PEDMARK® in the United States earned in the years ended December 31, 2022 and 2021, respectively:

	Year Ended	
In thousands	**December 31, 2022**	**December 31, 2021**
Product revenues:		
Gross product revenues	$ 1,769	$ —
Discounts and allowances	(234)	—
Net product revenues	$ 1,535	$ —

The following table summarizes the percentage of total product revenues for PEDMARK® in the United States by any Customer who individually accounted for 10% or more of total product revenues earned in the years ended December 31, 2022 and 2021, respectively:

	Year Ended	
In thousands	**December 31, 2022**	**December 31, 2021**
Cardinal Health Specialty	72 %	— %
ASD	16	—
	88 %	— %

The activities and ending allowance balances for each significant category of discounts and allowances for PEDMARK® (which constitute variable consideration) for the year ended December 31, 2022 were as follows:

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

In thousands	Chargebacks, Discounts for Prompt Pay and Other Allowances	Rebates, Customer Fees/Credits and Co-Pay Assistance	Totals
Balance at December 31, 2021	$ —	$ —	$ —
Provision related to sales made in:			
Current period	72	163	235
Prior periods	—	—	—
Payments and customer credits issued	(1)	—	(1)
Balance at December 31 2022	$ 71	$ 163	$ 234

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 considers its historical losses, if any, to estimate credit losses. The Customers are specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low.

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 (1% of net sales), payments 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 the Company's product. The Company considered regulatory approval of its product candidate 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 fourth quarter product launch. As of December 31, 2022, the Company capitalized approximately $0.6 million of costs as inventory on the Consolidated Balance Sheet. Of the items capitalized, $0.4 million was capitalized as work in process, $0.2 million was capitalized into finished goods, with $0.1 million 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. At December 31, 2022, the Company had $23.8 million in cash and money market accounts (2021- $21.1 million). 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 $250,000 amount insured by the FDIC and may lose value.

Financial Instruments

Financial instruments recognized on the balance sheets at December 31, 2022 and December 31, 2021 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

The Company has 0.2 million warrants with a weighted average strike price of $7.71 outstanding to purchase common shares that were denominated in United States dollars ("USD") and have a weighted average life of 5.05 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®. The Customers are a limited group of specialty distributors, and accordingly, the Company considers the risk of potential credit losses to be low.

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 December 31, 2022, and 2021, 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, we 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 Translation

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

Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted net 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 0.2 million of our common shares and options to purchase 4.5 million of our common shares at December 31, 2022, were not included in loss per share. Such options would have an antidilutive effect. In 2021, warrants to purchase 0.04 million of our common shares and options to purchase 4.3 million common shares were excluded from the computation of loss per share as their inclusion would have been antidilutive.

Recent Accounting Pronouncements

In May 2021, the FASB issued Accounting Standards Update ("ASU") 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU provides measurement guidance for a modification, or an exchange of a freestanding equity classified written call option that is not within the scope of another Topic. The Company adopted the ASU as of January 1, 2022 and its adoption did not have a significant impact on the Company's consolidated financial statements. The Company will apply the amendments prospectively to modifications or exchanges occurring on or after January 1, 2022.

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments – Credit Losses (Topic 326) and subsequently related amendments (ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11 and ASU 2022-02). This guidance replaces the existing incurred loss impairment guidance and establishes a single allowance framework for financial assets carried at amortized cost based on expected credit losses. The estimate of expected credit losses requires the incorporation of historical information, current conditions, and reasonable and supportable forecasts. This ASU will be effective for the quarter ended March 31, 2023. The Company is evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). The new standard eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. This ASU will be effective for the year ended December 31, 2024. The Company is currently evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

In June 2022, the FASB issued Accounting Standards Update ("ASU") 2022-03, Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which (1) clarifies the guidance in Topic 820 on the fair value measurement of an equity security that is subject to contractual restrictions that prohibit the sale of an equity security and (2) requires specific disclosures related to such an equity security. This ASU will be effective for the year ended December 31, 2024. The Company is currently evaluating the effect the adoption of this ASU will have on the consolidated financial statements.

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

3. Loss per Share

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

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (23,714)	$ (17,346)
Denominator:		
Weighted-average common shares, basic	26,275	26,006
Dilutive effect of stock options	—	—
Dilutive effect of warrants	—	—
Incremental dilutive shares	—	—
Weighted-average common shares, diluted	26,275	26,006
Net loss per share, basic and diluted	**$** (0.90)	**$** (0.67)

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

	Year Ended December 31,	
	2022	2021
Options to purchase common shares	4,539	4,259
Warrants to purchase common shares	150	39

4. Stock Options

The Compensation Committee of the Board of Directors administers the Company's stock option plan. The Compensation Committee designates eligible participants to be included under the plan and approves the number of options to be granted from time to time under the plan. On June 24, 2010, at the Company's annual meeting, shareholders approved an amendment to the Company's Stock Option Plan (the "Plan Maximum Amendment"). The Plan Maximum Amendment relates to changing the maximum number of common shares issuable under the stock option plan from a fixed number of 6.7 million to the number of shares that represents twenty-five percent (25%) of the total number of all issued and outstanding common shares. Based upon the current shares outstanding, a maximum of 6.6 million of our common shares are authorized for issuance under the plan. The option exercise price for all options issued under the plan is based on 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 stock option plan, as amended, allows the issuance of Canadian and U.S. dollar grants. A summary of the stock option transactions, U.S. dollar grants, for the years ended December 31, 2022 and 2021 is below. There are no outstanding $CAD denominated options.

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

Summary of $USD Option Activity

	Number of Options (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2020	**2,952**	**$ 0.45 – 12.59**	**$ 4.82**
Granted	1,412	4.08 – 7.53	5.93
Exercised	(11)	1.05 – 5.10	3.15
Forfeited	(94)	7.40 – 8.09	7.79
Outstanding and exercisable at December 31, 2021	**4,259**	**$ 0.45 – 12.59**	**$ 5.13**
Granted	1,015	5.59 - 8.10	6.50
Exercised	(273)	0.45 - 8.38	3.29
Forfeited	(462)	5.59 - 8.10	6.79
Outstanding and exercisable at December 31, 2022	**4,539**	**$ 0.45 – 12.59**	**$ 5.43**

Summary of $USD Option Remaining Life

Number Outstanding and Exercisable at December 31, 2022	Weighted Average Strike Price December 31, 2022	Weighted Average Remaining Life
(in thousands)	US Dollars	(years)
4,539	$5.43	6.67

Stock compensation expense for the fiscal years ended December 31, 2022 and 2021 was $4.2 million and $4.0 million, respectively. These amounts have been included in general and administrative expenses for the respective periods. The weighted average fair value per share of options granted and or vested during the fiscal years ended December 31, 2022 and 2021 was $5.43 and $5.93, respectively. The intrinsic value (being the difference between the share price at December 31, 2022 and exercise price) of stock options exercisable at December 31, 2022 was $15.63 million. The intrinsic value of options exercised during the fiscal year ended December 31, 2022 was $1.81 million.

The fair value of all options vested during the fiscal year ended December 31, 2022 was $3.8 million. The fair values of options granted in fiscal years ended December 31, 2022 and 2021 were estimated on the date the options were granted based on the Black-Scholes option-pricing model, using the following weighted average assumptions for all options with a ten-year expiration:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected dividend	0 %	0 %
Risk-free interest rate	1.18 - 3.96 %	1.41 - 1.62 %
Expected volatility	71 %	122 %
Expected life	5 - 6 years	10 years

The Company uses the historical volatility and adjusts for available relevant market information pertaining to the Company's share price.

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 years ended December 31, 2022 and 2021. All granted RSUs are denominated in U.S. dollars. Prior to June 2021, there was no activity involving RSUs. Of the 219 RSUs awarded, 86 were forfeited in fiscal year 2022 and 98 were released from restriction. The Company recognized $0.3 million in RSU expense for the year ended December 31, 2022 and $0.1 million for the same period in 2021. 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. There were 26 RSUs awarded to employees with standard vesting released from restriction in 2022. The Compensation Committee may also award RSUs with alternative

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

vesting. There were 34 RSUs awarded to various contractors which were released from restriction in 2022 on the one year anniversary of the award. There were 38 RSUs awarded to our CFO which conditionally released from restriction upon FDA approval of PEDMARK® in 2022. The Company recognized all of the expense associated with this release upon FDA approval of PEDMARK®.

US Denominated RSU's	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2020	**—**
Granted	219
Outstanding at December 31, 2021	**219**
Granted	—
Forfeited	(86)
Released	(98)
Outstanding at December 31, 2022	**35**

5. Fair Value Measurements

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

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

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

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

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 its Processa common shares 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 December 31, 2022, 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 year ended December 31, 2022, the Company did not have any transfers of financial assets between Levels 1 and 2.

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

Assets/Liabilities Measured at Fair Value on a Recurring Basis

	Fair Value Measurement at December 31, 2022 and December 31, 2021 (in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2022	2021	2022	2021	2022	2021	2022	2021
Assets								
Cash and cash equivalents	$ 307 (1)	82 (1)	23,467	21,018	—	—	23,774	21,100
Processa common shares	56 (2)	—	—	240	—	—	56	240

(1) The Company held approximately, $307 in cash as of December 31, 2022, of which approximately $33 was in Canadian funds (translated into U.S. dollars). As of December 31, 2021, the Company held approximately $82, of which approximately $34 was in Canadian funds (translated into U.S. dollars).

(2) The Company received 41 restricted common shares of Processa (PSCA). The share restriction expired in three tranches: 50%, 25% and 25% at the 6, 9 and 12 month intervals, respectively from October 30, 2020. As of December 31, 2022, the restrictions have expired.

6. Stockholders' Equity

Authorized Capital Stock

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

Warrants to Purchase Common Shares

At December 31, 2022, the Company had 150 warrants outstanding to purchase common shares at a weighted average exercise price of $7.71.

The following table summarized our warrant activity for the fiscal years ended December 31, 2022 and 2021.

	Number of Warrants (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2020	**$ 39**	**$ 6.80**	**$ 6.80**
Granted	—	—	—
Outstanding and exercisable at December 31, 2021	**$ 39**	**$ 6.80**	**$ 6.80**
Granted	111	8.11	8.00
Outstanding and exercisable at December 31, 2022	**$ 150**	**$ 7.71**	$ **7.71**

7. Commitments and Contingencies

Oregon Health & Science University ("OHSU") 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 $15 (1% net sales) in royalty expense to OHSU at December 31, 2022.

Leases

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

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

Securities Class Action Suit

Chapman v. Fennec Pharmaceuticals Inc. et al.

On September 3, 2020, plaintiff Jim Chapman filed a putative federal securities class action lawsuit against the Company, our Chief Executive Officer, Rostislav Raykov, and Chief Financial Officer, Robert Andrade, in the United States District Court for the Middle District of North Carolina, captioned *Chapman v. Fennec Pharmaceuticals Inc. et al*., Case No. 1:20-cv-00812. The complaint alleged that prior to our August 10, 2020 receipt of a CRL from the FDA concerning our NDA for PEDMARK®, defendants made materially false or misleading statements and failed to disclose material facts about our third-party PEDMARK® product manufacturing facility and the impact the facility would have on regulatory approval for PEDMARK®. On December 3, 2020, the court appointed a lead plaintiff to represent the putative class. On February 1, 2021, the lead plaintiff filed an amended complaint. The amended complaint added members of our Board of Directors as defendants, asserts a putative class period from December 20, 2018 through August 10, 2020, makes allegations similar to those in the original complaint, claims the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, and seeks an unspecified amount of compensatory damages and attorneys' fees and costs.

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

On March 30, 2022, lead plaintiff filed a motion for post judgment relief, seeking leave to file a second amended complaint. In his proposed second amended complaint, lead plaintiff seeks to add allegations stemming from the receipt of a second CRL following our resubmission of our NDA for PEDMARK®, which we received on November 29, 2021, among other things. Defendants filed an opposition to plaintiff's motion for post judgment relief on April 20, 2022. On May 4, 2022, lead plaintiff submitted a reply in support of his motion. On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it has approved PEDMARK®. On October 18, 2022, lead plaintiff filed his opposition to request for judicial notice. On October 21, 2022, defendants filed a reply in support of the request for judicial notice. On February 15, 2023, the Magistrate Judge recommended the motion for post judgment relief be denied. Lead plaintiff filed no timely objection to the recommendation, and on March 2, 2023, the U.S. District Court Judge issued an order adopting the Magistrate Judge's recommendation, denying the motion for post judgment relief, and entering judgment for defendants.

We believe that this lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of December 31, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

Fisher v. Fennec Pharmaceuticals Inc. et al.

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

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

On September 27, 2022, defendants filed a request for judicial notice regarding the FDA's press release announcing that it approved PEDMARK® On September 30, 2022, lead plaintiff filed an opposition to the request for judicial notice. On October 6, 2022, defendants filed a reply in support of the request for judicial notice. On October 12, 2022, the U.S. District Court Judge issued a memorandum opinion and order dismissing the amended complaint in its entirety and with prejudice, and on October 14, 2022, entered judgment. Lead plaintiff had until November 14, 2022 to file a notice of appeal and did not file a notice of appeal.

We believe that the lawsuit is without merit and intend to defend it vigorously. We cannot predict the outcome of this lawsuit. Failure by us to obtain a favorable resolution of the lawsuit could have a material adverse effect on our business, results of operations, and financial condition. We have not recorded a liability as of December 31, 2022, because we believe a potential loss is not probable or reasonably estimable given the nature of the proceedings and our success so far by obtaining a dismissal with prejudice of the amended complaint.

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

On October 29, 2021, Hope Medical Enterprises, Inc. ("Hope") filed two petitions for inter partes review ("IPR") with the Patent Trial and Appeal Board ("PTAB") of the USPTO. In its petitions, Hope seeks to invalidate our U.S. Patent

No. 10,596,190 ("US '190 Patent"), which is exclusively in-licensed from Oregon Health & Science University ("OHSU") and relates to a method of using our PEDMARK® product, and our U.S. Patent No. 10,792,363 ("US '363 Patent"), which relates to an anhydrous form of STS and its method of manufacture, which is the active pharmaceutical ingredient in our PEDMARK® product. The US '190 Patent was issued on March 24, 2020. The US '363 Patent was issued on October 6, 2020.

On January 11, 2022, OHSU filed a Request for Supplemental Examination of US '190 Patent (Control No. 96.000,390) requesting the consideration by the Central Re-examination Unit ("CRU") of the USPTO of certain prior art references, including references cited by Hope in its Petition for IPR that are relevant to the granted claim of the patent. On January 28, 2022, the CRU issued a Supplemental Examination Certificate, identified a Substantial New Question ("SNQ") on the patentability of the US '190 Patent claims, and ordered a Reexamination of US '190 Patent on March 9, 2022. On May 9, the PTAB granted Hope Medical's Petition to Institute the IPR against the US '190 Patent and a stayed the US '190 Patent Reexamination pending the result of the US '190 Patent IPR. On August 12, 2022, OHSU filed a Motion to Amend the single claim of the US '190 Patent in the IPR to focus on the treatment of medulloblastoma. On December 5, 2022, OHSU filed a Revised Motion to Amend the single claim of the US '190 Patent. We expect a decision in the '190 Patent IPR in May 2023, which can be appealed by the losing party.

Further, in May 2022, the PTAB granted Hope Medical's Petition to Institute the IPR against the '363 Patent. During the '363 Patent IPR, we disclaimed the '363 Patent claims directed to the anhydrous morphic form of STS, and filed a Motion to Amend the remaining method of manufacture claims. On December 14, 2022, we filed a Revised Motion to Amend the remaining claims in the '363 Patent. We expect a decision in the '363 IPR in May 2023, which can be appealed by the losing party.

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

CIPLA ANDA 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 US '190 Patent, expiration date January 2038; and our US 11,291,728 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. 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. 3:23-cv-00123), for infringement of the '190 Patent and the '728 Patent. The suit is ongoing.

Executive Severance

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

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 Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. As of December 31, 2022 the Company does not offer matching contributions.

8. 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. 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 Second Closing Trigger.

Subsequent to the funding of the Second Closing Note, and before December 31, 2023, the Company may draw up to $20,000 of additional financing under the SPA, in one or more tranches of $10,000 upon mutual agreement of the Company and the 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 is payable under the SPA. Half of such fee was paid by the issuance on the first closing of warrants to purchase 55,498 Fennec common shares and half was payable in cash or warrants of 55,498 Fennec common shares, at our election, on the second closing. The Company chose to issue warrants to satisfy the payable on both the first and second closing. The warrants are exercisable at a price per share of $8.11 and respectively, and both have a maturity date of August 19, 2027.

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 December 31, 2022). 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 $0.26 in PIK interest and has classified the PIK interest in long-term liabilities.

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

Aggregate annual payments due on the SPA as of December 31, 2022, are as follows (in thousands):

Years Ending December 31,	**Amount**
2022	—

2023	—
2024	—
2025	—
2026	—
2027	25,000
Total future payments	25,000
Add: PIK interest	260
Less: unamortized debt discount	(361)
Total term loan, net of debt discount	$ 24,899

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.

9. Income Taxes

The Company operates in both U.S. and Canadian tax jurisdictions. Its income is subject to varying rates of tax and losses incurred in one jurisdiction cannot be used to offset income taxes payable in another. A reconciliation of the combined Canadian federal and provincial income tax rate with the Company's effective tax rate is as follows (in thousands except for percentage rates):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Domestic loss	$ (10,548)	$ (9,122)
Foreign loss	(13,117)	(8,173)
Loss before income taxes	(23,665)	(17,295)
Expected statutory rate	26.50 %	26.50 %
Expected provision for (recovery of) income tax	(6,271)	(4,583)
Permanent differences	1,170	993
Change in valuation allowance	4,669	3,086
Effect of foreign exchange rate differences		—
Effect of change in future enacted tax rates		—
Tax credits and other adjustments		—
Effect of tax rate changes and other	432	504
Provision for income taxes	$ —	$ —

The Canadian statutory income tax rate of 26.5 percent is comprised of federal income tax at approximately 15.0 percent and provincial income tax at approximately 11.5 percent.

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

The primary temporary differences which gave rise to future income taxes (recovery) at December 31, 2022 and December 31, 2021:

	December 31, 2022	December 31, 2021
Future tax assets:		
SR&ED expenditures	$ 2,086	$ 2,086
Income tax loss carryforwards	34,948	30,007
Non-refundable investment tax credits	421	700
Share issue costs	62	77
Fixed and intangible assets	1,083	1,083
Debt discount	22	—
	38,622	33,953
Less: valuation allowance	(38,596)	(33,927)
Net future tax assets	$ 26	$ 26

10. Subsequent Events

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

Tax Cuts and Jobs Act

On December 22, 2017, the then President of the United States signed into law an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018 (commonly known as “the Tax Cuts and Jobs Act” (“TCJA”)), which introduced a comprehensive set of tax reforms. The Tax Cuts and Jobs Act significantly revises U.S. tax law by, among other provisions, lowering the Company’s corporate tax rate from 34% to 21% and eliminating or reducing certain income tax deductions.

In December 2017, in accordance with the SEC Staff Accounting Bulletin (“SAB”) 118–Income Tax Accounting Implications of the TCJA, the Company recorded tax effects on a provisional basis based on a reasonable estimate. The TCJA did not have a material impact on the Company's financial statements because its deferred temporary differences are fully offset by a valuation allowance and the Company does not have any offshore earnings from which to record the mandatory transition tax. During 2018, the Company completed its analysis under SAB 118 and no additional tax effects due to rate-remeasurement were required to be recorded.

There are no current income taxes owed, nor are any income taxes expected to be owed in the near term. At December 31, 2022, the Company has unclaimed Scientific Research and Experimental Development ("SR&ED") expenditures, income

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

tax loss carry-forwards and non-refundable investment tax credits. The unclaimed amounts and their expiry dates are as listed below:

	Federal	Province/ State
SR&ED expenditures (no expiry)	$ 7,872	$ —
Income tax loss carryforwards (expiry date):		
2023	1,588	—
2024	4,849	—
2025	6,143	—
2026	13,868	—
2027	8,136	—
2028	10,509	4,164
2029	8,185	2,116
2030	2,608	700
2031	3,378	789
2032	3,491	651
2033	1,789	655
2034	1,812	617
2035	1,804	941
2036	2,208	1,013
2037	4,641	1,638
2038	5,267	-
2039	5,848	-
2040	5,792	-
2041	5,340	-
2042	6,192	-
No expiration	35,974	24,580
Investment tax credits (expiry date):		
2023	169	
2024	189	
2025	82	
2026	86	
2027	47	

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-221091 and 333-232353) and the Registration Statements on Form S-3 (File Nos. 333-268632, 333-219884 and 333-249775) of Fennec Pharmaceuticals Inc. (the "Company") of our report dated March 29, 2023, relating to the consolidated financial statements as of December 31, 2022 and 2021 and for each of the years then ended, which appear in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
March 29, 2023

Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Rostislav Raykov, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2022 of Fennec Pharmaceuticals Inc.;

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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 consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual 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 Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

   (d) Disclosed in this Annual 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.

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: March 29, 2023

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

Exhibit 31.2

FENNEC PHARMACEUTICALS INC.
CERTIFICATION

I, Robert Andrade, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2022 of Fennec Pharmaceuticals Inc.;

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual 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 consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual 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 Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

   (d) Disclosed in this Annual 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.

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: March 29, 2023

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

Exhibit 32.1

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

In connection with the Annual Report of Fennec Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 (the "Report"), each of the undersigned, Rostislav Raykov, Chief Executive Officer of the Company, and Robert Andrade, Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2023

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

Date: March 29, 2023

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

FENNEC PHARMACEUTICALS REPORTS FULL YEAR AND FOURTH QUARTER 2022 FINANCIAL RESULTS

~ U.S. Commercial Team in Place with PEDMARK® Launch Off to Solid Start Following FDA Approval of PEDMARK® in September 2022 ~

~ Company Has Approximately $23.8 Million in Cash ~

Research Triangle Park, NC, March 30, 2023 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the fiscal year ended December 31, 2022 and provided a business update.

"It was an outstanding year for Fennec as we achieved FDA approval of PEDMARK® in the fourth quarter and evolved into a commercial-stage pharmaceutical company. For 2023, we are focused on building upon our early commercial launch momentum by continuing to execute on our strategic plans, expand our prescriber base, and increase the utilization of PEDMARK®," said Rosty Raykov, chief executive officer of Fennec Pharmaceuticals. "We are very proud of Fennec's patient-centric approach and the performance across the entire organization, and we continue to be motivated by the positive responses that we are receiving from the pediatric cancer patient community, healthcare providers and payors. Fennec remains dedicated to growing its revenues both in the U.S. and worldwide as we seek to expand PEDMARK's presence and availability to patients globally."

Recent Developments and Highlights:

- Received U.S. Food and Drug Administration (FDA) approval of the PEDMARK® New Drug Application (NDA) on September 20, 2022. PEDMARK® is the first and only FDA-approved therapy indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors.

- Initiated U.S. commercial launch of PEDMARK® on October 17, 2022. The Fennec HEARS™ program offers comprehensive patient services, including access to care coordinators, financial and prescription drug support.

- The National Comprehensive Cancer Network® (NCCN) updated its clinical practice guidelines for Adolescent and Young Adult (AYA) Oncology to include PEDMARK® (sodium thiosulfate injection) in January 2023.

- The FDA granted Orphan Drug Exclusivity to PEDMARK® (sodium thiosulfate injection) in January 2023. The FDA's Orphan Drug Designation program is designed to advance the development of drugs that treat a condition affecting 200,000 or fewer U.S. patients annually. The seven-year market exclusivity for PEDMARK® began on September 20, 2022, the date of its FDA approval, and continues until September 20, 2029. Additionally, in the approved prescribing label, the FDA has explicitly directed that PEDMARK® is not substitutable with other sodium thiosulfate products.[1]

Financial Results for the Fourth Quarter and Fiscal Year Ended December 31, 2022

- **Cash Position –** There was a $2.7 million increase in cash and cash equivalents between December 31, 2022 and December 31, 2021. The net increase was the result of cash operating expenses, offset by the net $20.0 million received from the Petrichor note and $0.9 million received from the exercise of 273,000 options. During the period ended December 31, 2022, cash for operations was used mainly on the pre-commercialization activities of PEDMARK® prior to FDA approval and then commercialization activities post NDA approval.

- Commercial launch of PEDMARK® commenced in October 2022. The company recorded net product sales of $1.54 million in fiscal 2022. The Company recorded discounts and allowances against sales in the amount of $0.2 million and cost of products sold of $0.1 million. The Company had gross profit of $1.4 million for fiscal year ended 2022. In fiscal 2021, the Company had no revenues.

- **Research and Development (R&D) Expenses** – R&D expense decreased by $1.5 million in fiscal 2022 as compared to fiscal 2021. The Company reduced research and development costs when it received FDA approval of PEDMARK®. The majority of traditional research and development expenses associated with PEDMARK® are now recorded as general and administrative expenses or capitalized into inventory and eventually recorded to costs of product sales.

- **Selling and Marketing (S&M) Expenses** – The Company began recording selling and marketing expenses when it expanded its payroll to include an internal salesforce. Selling and marketing expenses include distribution costs, logistics, shipping and insurance, advertising, wages commissions and out-of-pocket expenses. The Company recorded $2.8 million in selling and marketing expenses in fiscal 2022.

- **General and Administrative (G&A) Expenses –** There was a $5.5 million increase in general and administrative expenses in fiscal 2022 compared to fiscal 2021. Payroll and benefits related expenses rose by $4.0 million in fiscal 2022 compared to fiscal 2021 as our headcount increased from 10 to 36 over the course of fiscal 2022. There was an increase in legal costs of $1.4 million in fiscal 2022 over fiscal 2021. This net increase is comprised of an increase in $0.2 million in class action suit defense, a decrease in general legal expense of $0.2 million and an increase of $1.4 million in intellectual property litigation. Pre-commercialization activities rose by $0.2 million in fiscal 2022 over fiscal 2021. Non-cash expenses associated with equity remuneration increased by $0.2 million.

- **Net Loss -** Net losses for the fourth quarter and year ended December 31, 2022 of $6.9 million ($0.26 per share) and $23.8 million ($0.90 per share), respectively, compared to $4.4 million ($0.18 per share) and $17.3 million ($0.67 per share), respectively, for the same periods in 2021.

- **Financial Guidance –** The Company believes its cash and cash equivalents on hand as of December 31, 2022 will be sufficient to fund the Company's planned commercial activities for 2023.

Financial Update

The selected financial data presented below is derived from our audited, condensed consolidated financial statements, which were prepared in accordance with U.S. generally accepted accounting principles. The complete audited, condensed consolidated financial statements for the period ended December 31, 2022, and management's discussion and analysis of financial condition and results of operations, will be available via www.sec.gov and www.sedar.com. All values are presented in thousands unless otherwise noted.

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

	Three Months Ended		Twelve Months Ended	
	December 31, 2022	December 31, 2021	December 31, 2022	December 31, 2021
Revenue				
PEDMARK product sales, net	$ 1,535	$ —	$ 1,535	$ —
Cost of products sold	(86)	—	(86)	—
Gross profit	1,449	—	1,449	—
Operating expenses:				
Research and development	117	523	3,531	4,981
Selling and marketing	2,785	—	2,785	—
General and administrative	4,682	3,684	17,722	12,242
Total operating expenses	7,584	4,207	24,038	17,223
Loss from operations	(6,135)	(4,207)	(22,589)	(17,223)
Other (expense)/income				
Unrealized foreign exchange loss	(58)	(162)	(9)	(10)
Amortization expense	(70)	(8)	(149)	(16)
Unrealized (loss) on securities	(3)	(1)	(184)	(25)
Interest income	153	13	195	54
Interest expense	(744)	(62)	(978)	(126)
Total other (expense)/income	(722)	(220)	(1,125)	(123)
Net loss	$ (6,857)	$ (4,427)	$ (23,714)	$ (17,346)
Basic net loss per common share	$ (0.26)	$ (0.18)	$ (0.90)	$ (0.67)
Diluted net loss per common share	$ (0.26)	$ (0.18)	$ (0.90)	$ (0.67)
Weighted-average number of common shares outstanding basic	26,275	26,011	26,113	26,006
Weighted-average number of common shares outstanding diluted	26,275	26,011	26,113	26,006

Audited Consolidated Balance Sheets:
(U.S. Dollars in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 23,774	$ 21,100
Accounts receivable, net	1,545	—
Prepaid expenses	770	1,034
Inventory	576	—
Other current assets	63	253
Total current assets	26,728	22,387
Non-current assets		
Deferred issuance cost, net amortization	211	27
Total non-current assets	211	27
Total assets	$ 26,939	$ 22,414
Liabilities and shareholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,390	$ 777
Accrued liabilities	2,219	877
Total current liabilities	4,609	1,654
Long term liabilities		
Term loan	25,000	5,000
PIK interest	260	—
Debt discount	(361)	(12)
Total long term liabilities	24,899	4,988
Total liabilities	29,508	6,642
Commitments and Contingencies		
Shareholders'(deficit) equity:		
Common stock, no par value; unlimited shares authorized; 26,361 shares issued and outstanding (2021 -26,014)	142,591	140,801
Additional paid-in capital	56,797	53,214
Accumulated deficit	(203,200)	(179,486)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' (deficit) equity	(2,569)	15,772
Total liabilities and shareholders' (deficit) equity	$ 26,939	$ 22,414

Working capital	Fiscal Year Ended	
Selected Asset and Liability Data:	**December 31, 2022**	**December 31, 2021**
(U.S. Dollars in thousands)		
Cash and equivalents	$ 23,774	$ 21,100
Other current assets	2,954	1,287
Current liabilities	(4,608)	(1,654)
Working capital	$ 22,120	$ 20,733
Selected Equity:		
Common stock and additional paid in capital	199,388	194,015
Accumulated deficit	(203,200)	(179,486)
Shareholders' equity	(2,569)	15,772

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.[i]

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.[ii] 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.[iii]

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.[7] 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^2.

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.

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

Forward Looking Statements
Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK®, the market opportunity for and market impact of PEDMARK®, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2022. Fennec disclaims any obligation to update these forward-looking statements except as required by law.

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

PEDMARK® and Fennec® are registered trademarks of Fennec Pharmaceuticals Inc.

For further information, please contact:

Investors:
Robert Andrade
Chief Financial Officer

Fennec Pharmaceuticals Inc.
+1 919-246-5299

Corporate and Media:
Lindsay Rocco
Elixir Health Public Relations
+1 862-596-1304
lrocco@elixirhealthpr.com

---

[i] Rybak L. Mechanisms of Cisplatin Ototoxicity and Progress in Otoprotection. Current Opinion in Otolaryngology & Head and Neck Surgery. 2007, Vol. 15: 364-369.
[ii] Landier W. Ototoxicity and Cancer Therapy. *Cancer*. June 2016 Vol. 122, No.11: 1647-1658.
[iii] 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.