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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, 2025

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, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was $106,052,055 based upon a total of 12,777,356 shares held as of June 30, 2025 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 20, 2026, there were 34,475,178 shares of the registrant's Common Shares outstanding.

FENNEC PHARMACEUTICALS INC.
2025 FORM 10-K ANNUAL REPORT
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PART I

Item 1. Business

You are urged to read this Annual Report on Form 10-K ("Annual Report") in its entirety. "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 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."

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 additional regulatory approvals 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 may 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 involves environmental risks and potential exposure to environmental liabilities.

Risks Related to Marketing Approval of Our Product

- PEDMARK® has received marketing approval from the FDA and from the European Commission, but not from any additional 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

- 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.
- A pandemic or epidemic (including were there to be a resurgence of the 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.
- Although we have received regulatory approvals for PEDMARK®, it still remains 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.
- Our strategy depends in part on the efforts of third party development partners to obtain regulatory approvals and commercialize PEDMARK® outside the United States, including Norgine Pharma UK Limited ("Norgine") in Europe and Inpharmus (formerly TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC) ("Inpharmus") in Turkey and Gulf Cooperation Council ("GCC") countries. Our ability to realize revenues from these territories will depend on the performance of these partners, the timing and outcome of local regulatory submissions, and

the pricing and reimbursement decisions in each country. If our partners do not successfully obtain approvals, secure adequate reimbursement, or effectively commercialize PEDMARK® in their territories, or if our relationships with them are disrupted, our business, results of operations and prospects could be adversely affected.

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 approvals for PEDMARK®, 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.

Risks Related to Information Technology

- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

- Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

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

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.

Overview

Fennec Pharmaceuticals Inc., a corporation existing under the laws of British Columbia, was originally formed under the name Adherex Technologies Inc. and subsequently changed its name on September 3, 2014. Fennec is a commercial stage specialty pharmaceutical company dedicated to preventing cisplatin-induced ototoxicity ("CIO"), a serious and often irreversible side effect of cancer treatment, with one FDA approved and European Commission approved product, PEDMARK® in the U.S. and PEDMARQSI®, which is the branded name for PEDMARK® in Europe, the U.K., Australia and New Zealand (collectively, "PEDMARK"), developed to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. The Company has four wholly owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian corporation, and Fennec Pharmaceuticals (EU) Limited, an Ireland company ("Fennec Limited"). With the exception of Fennec Pharmaceuticals, Inc. and Fennec Limited, all subsidiaries are inactive. On September 20, 2022, we received approval from the FDA for PEDMARK® (sodium thiosulfate injection). This approval makes PEDMARK® the first and only treatment approved by the FDA in this area of significant unmet medical need. On October 17, 2022, we announced commercial availability of PEDMARK® in the United States. Further, PEDMARQSI® received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

PEDMARK® is currently the 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. In clinical studies in this population, treatment with PEDMARK® resulted in an approximate 50% relative reduction in the incidence of cisplatin-induced hearing loss compared to cisplatin alone, without evidence of materially compromised antitumor efficacy. PEDMARK® is administered as a short intravenous infusion and has generally been associated with a mild-to-moderate and manageable safety profile consistent with its known pharmacology.

In March 2024, we announced that we entered into an agreement with Norgine, a leading European specialist pharmaceutical company. This is an exclusive licensing agreement under which Norgine will commercialize PEDMARQSI® in Europe, Australia and New Zealand. PEDMARQSI® is the first and only approved therapy in the EU and U.K. for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients one month to eighteen years of age with localized, non-metastatic solid tumors. During 2025, Norgine made PEDMARQSI® commercially available and expects additional launches to occur in 2026 and beyond.

Under the terms of the Norgine licensing agreement, Fennec received approximately $43 million in upfront consideration and may receive up to approximately $230 million in additional commercial and regulatory milestone payments and double-digit tiered royalties (up to the mid-twenties) on net sales of PEDMARQSI® in the licensed territories. To date, Fennec has not received any milestone payments. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

In the United States, we sell our product through an experienced field force including Regional Pediatric Oncology Specialists and we utilize medical science liaisons within our medical team who help educate the medical communities and patients about CIO 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 PEDMARK® 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 six patents listed for PEDMARK® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book"). In September 2022, the United States Patent and Trademark Office ("USPTO") issued Patent No. 11,291,728 (the "US '728 Patent"), in December 2022, the USPTO issued Patent No. 11,510,984 ("US '984 Patent") and in April 2023, the USPTO issued Patent No. 11,671,793 ("US '793 Patent") that covers PEDMARK® pharmaceutical formulation. Further, additional issued patents included US 11,964,018 Patent (the "US '018 Patent) and US 11,992,530 Patent (the "US '530 Patent") and US 11,998,604 Patent (the "US '604 Patent") covering methods of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '728, US '984, US '793, US '018, US '530, and US '604 Patents will expire in 2039. Additional patents covering PEDMARK® formulation have been granted in Australia, Canada, the European Patent Office (EPO) (described further below), Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, and Russia, and patent applications covering PEDMARK® are pending in Brazil, China, the European Patent Office (EPO), Hong Kong, Israel, Korea, Mexico, New Zealand, Singapore, and Thailand. Patents covering alternative sodium thiosulfate formulations have been granted in the United States (US 12,311,026 (the "US '026 Patent"), Canada, Korea, Mexico, and Russia, and patent applications covering alternative sodium thiosulfate formulations are pending in the United States, Australia, the EPO, Hong Kong, Indonesia, Japan, Malaysia, Mexico, and New Zealand. Applications from these patent families, where granted, valid, and enforceable, will expire in July 2039, exclusive of any patent term adjustment or extension

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® 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 cancer patients 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.

In the United States, PEDMARK® is the first and only therapy approved to mitigate the risk of ototoxicity associated with cisplatin in pediatric patients aged one month and older with localized, non-metastatic solid tumors. Further, the National Comprehensive Cancer Network (NCCN) recommended the use of PEDMARK® to reduce the risk of cisplatin-induced ototoxicity in patients with localized, non-metastatic solid tumors (category 2A) for Adolescent and Young Adult (AYA) Oncology. As of January 2025, all medical compendia have incorporated Fennec's clinical updates, and AHFS, the largest online platform for pharmacists, has updated its content to reflect and differentiate PEDMARK® in accordance with its labeling.

PEDMARK® is the first and only FDA- and EMA-approved agent designed to reduce the risk of CIO in pediatric patients with localized solid tumors. The strategic imperatives driving the execution of PEDMARK®'s strategy include increasing awareness of unmet patient needs and emphasizing the importance of preventing CIO among oncologists. A key goal is to establish PEDMARK® as the standard of care (SOC) for all CIO prevention. Additionally, efforts focus on expanding adoption beyond oncologists by ensuring healthcare providers (HCPs) gain confidence in and have positive experiences with PEDMARK®. Ensuring seamless access for advocacy groups, payers, and providers is also a priority, along with activating patients and caregivers through disease education to drive demand for PEDMARK®. Key activities supporting these objectives include an expanded sales team with a strong track record in both academic and community settings, partnerships with group purchasing organizations, and specialty pharmacy offerings such as home infusions, white bag delivery, and direct billing. Furthermore, digital materials, a digital speaker bureau to engage pediatric oncologists, audiologists, nurses, and pharmacists, along with a patient access services hub and ongoing support from advocacy groups, are all integral components of the strategy.

In the U.S. and Europe, Fennec estimates that there are approximately 11,400 pediatric patients with localized, non-metastatic solid tumors each year, of which include approximately 2,157 cisplatin-treated pediatric patients in the U.S. and 1,250 in Europe who fall within the current PEDMARK® market. The incidence and severity of CIO depends on the cumulative dose and duration of chemotherapy. Many affected children ultimately require hearing aids or, in more severe cases, cochlear implants, which are costly, technically complex and do not fully restore normal hearing. PEDMARK® is the first and only therapy approved in the U.S. to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. Infants and young children who experience ototoxicity during critical developmental windows are at risk for impaired speech and language development and literacy, while older children and adolescents may face long-term challenges in academic performance, social-emotional development, career potential and independent living.

In the U.S., approximately 90% of pediatric cancer patients receive care at approximately 200 key pediatric hospital centers, including institutions within the Children's Oncology Group (COG), National Cancer Institute (NCI) and National Comprehensive Cancer Network (NCCN).

The Adolescent and Young Adult ("AYA") oncology patient is defined as an individual between 15 and 39 years of age at the time of initial cancer diagnosis. In the U.S., Fennec estimates that there are approximately 51,282 new AYA solid tumor cases annually, of which approximately 20,858 involve cisplatin-treated patients with localized, non-metastatic solid tumors. The most common relevant tumor types include germ cell tumors, testicular cancer, thyroid cancer and breast cancer. The U.S. AYA oncology treatment landscape spans both academic and community settings, with 72 NCI-designated academic centers treating roughly 20% of AYA oncology patients, while approximately 80% are managed across approximately 3,750 community oncology centers nationwide.

CIO and Unmet Medical Need

Cisplatin is a cornerstone of modern cancer therapy for many pediatric and AYA solid tumors, with reported overall survival rates in some cisplatin-treated cancers exceeding 80%. However, cisplatin is associated with a high incidence of ototoxicity. Published data indicates that approximately 60% to 90% of cisplatin-treated patients may develop some degree of permanent, sensorineural hearing loss, with reported rates of 40% to 80% occurring in adults and 50% to 90% in children. CIO typically begins as bilateral, high-frequency hearing loss that is progressive and irreversible, occasionally accompanied by tinnitus. In some cases, it may ultimately require the use of hearing aids or cochlear implants.

Published literature has linked treatment-related hearing loss to impairments in speech and language development, reduced academic performance, challenges in social-emotional development, and enduring impacts on educational attainment, vocational opportunities, and independent living. Additionally, published research indicates that severe to profound early-onset hearing loss can impose a substantial lifetime economic burden, with per-individual costs estimated at approximately $489 and potentially exceeding $1,000 on an undiscounted basis, primarily due to lost productivity, educational expenses, and medical costs. These figures are derived from published literature regarding the disease burden of hearing loss and do not represent demonstrated health-economic outcomes specifically attributable to PEDMARK.

European Commission Marketing Authorization

PEDMARQSI® (PEDMARK® brand name in Europe) received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

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

Under the terms of the licensing agreement, Fennec received approximately $43 million in upfront consideration and may receive up to approximately $230 million in additional commercial and regulatory milestone payments and double-digit tiered royalties on net sales of PEDMARQSI® in the licensed territories up to the mid-twenties. To date, Fennec has not received any milestone payments. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

In December 2024, PEDMARQSI® received positive final draft guidance from the National Institute for Health and Care Excellence (NICE). Most recently, in 2025, Norgine launched PEDMARQSI® in Germany and the U.K with additional countries within the EU expected in 2026.

Distribution Agreement – Turkey and the Gulf Cooperation Council

In 2025, we entered into a distribution agreement with Inpharmus for the commercialization of PEDMARK® in Turkey and the GCC countries. Under this agreement, Inpharmus will be responsible for certain regulatory, commercialization and distribution activities in the covered territories, and we will supply PEDMARK® and receive payments, subject to specified terms and conditions. Commercialization in these markets is subject to obtaining and maintaining necessary regulatory approvals and reimbursement, and there can be no assurance as to the timing or magnitude of future revenues, if any, from these territories.

Japan: STS-J01 Investigator-Initiated Trial and Registration Plans

In Japan, an independent investigator-initiated clinical trial, known as STS-J01, has been evaluating PEDMARK® for the prevention of CIO. In December 2025, we announced positive topline results from this trial that demonstrated use of PEDMARK® was associated with a significant reduction in the incidence of hearing loss compared to historically reported rates in patients receiving cisplatin alone, with no evidence of reduced antitumor activity and an approximate 95% clinical response rate. Based on these results, we are pursuing a regulatory registration strategy for PEDMARK® in Japan and are evaluating partnering or licensing opportunities in that market, similar to our model with Norgine in Europe. Any such

registration and partnering activities will be subject to applicable regulatory requirements and successful negotiations with potential partners.

Investigator-Initiated Studies and Lifecycle Management

In addition to our pivotal pediatric studies (SIOPEL6 and COG ACCL0431), we support a number of investigator-initiated and other clinical studies designed to further characterize the use of PEDMARK® in additional tumor types and patient populations. For example, City of Hope, a U.S. cancer research and treatment organization, is conducting an investigator-initiated clinical trial evaluating PEDMARK® in adult men with stage II–III metastatic testicular germ cell tumors receiving cisplatin-based chemotherapy. We also engage in medical affairs activities and data-generation initiatives to expand the clinical evidence base for PEDMARK®, including in AYA and adult populations. These studies are exploratory in nature, and PEDMARK® is not currently approved for use in metastatic cancers or adult populations outside of its labeled indication. Any potential label expansion will require additional clinical data and regulatory approvals.

Commercial Infrastructure and Patient Support Programs

During 2025, we significantly expanded our commercial infrastructure and patient support capabilities. Our Fennec HEARS® program provides comprehensive education, access, and reimbursement assistance to patients and healthcare providers. The program includes:

- Financial support: A $0 copay savings program for eligible patients with commercial or private insurance and the Fennec Patient Assistance Program for eligible patients without insurance.
- Patient and product support: Dedicated care coordinators to answer insurance questions, assist with prior authorizations, and provide treatment resources.
- Distribution network: Established third-party logistics providers (3PL) and specialty pharmacy partnerships with home infusion support capabilities.
- Provider engagement: Peer-to-peer speaker bureau, medical science liaison (MSL) team, and comprehensive marketing initiatives across multiple channels.

We have achieved formulary adoption at certain large oncology networks and academic institutions, with successful activations in both academic centers and community oncology practices occurring throughout 2025.

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, U.K., 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 have six patents listed for PEDMARK® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book"). In September 2022, the United States Patent and Trademark Office ("USPTO") issued Patent No. 11,291,728 (the "US '728 Patent"), in December 2022, the USPTO issued Patent No. 11,510,984 ("US '984 Patent") and in April 2023, the USPTO issued Patent No. 11,671,793 ("US '793 Patent") that covers PEDMARK® pharmaceutical formulation. Further, additional issued patents included US 11,964,018 Patent (the "US '018 Patent) and US 11,992,530 Patent (the "US '530 Patent") and US 11,998,604 Patent (the "US '604 Patent") covering methods of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '728, US '984, US '793, US '018, US '530, and US '604 Patents will expire in 2039. Additional patents covering PEDMARK® formulation have been granted in Australia, Canada, the European Patent Office (EPO) (described further below), Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, and Russia, and patent applications covering PEDMARK® are pending in Brazil, China, the European Patent Office (EPO), Hong Kong, Israel, Korea, Mexico, New Zealand, Singapore, and Thailand. Patents covering alternative sodium thiosulfate formulations have been granted in the United States (US 12,311,026 (the "US '026 Patent"), Canada, Korea, Mexico, and Russia, and patent applications covering alternative sodium thiosulfate formulations are pending in the United States, Australia, the EPO, Hong Kong, Indonesia, Japan, Malaysia, Mexico, and New Zealand. Applications from these patent families, where granted, valid, and enforceable, will expire in July 2039, exclusive of any patent term adjustment or extension.

On June 18, 2025, the European Patent Office issued European Patent No 3817751B, which covers the pharmaceutical formulation of PEDMARQSI® (EU Brand name for PEDMARK®). This patent has been validated in the following designated European countries: Albania, Austria, Belgium, Bulgaria, Cyprus, Switzerland, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Great Britain, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherland, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey, as well as the extension countries of Bosnia and Herzegovina, Moldova, Montenegro, Morocco and Tunisia. This patent will expire in July 2039, unless held invalid or unenforceable by a court of final jurisdiction.

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.

Fennec's Sodium Thiosulfate Patents and 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 April 4, 2023, the USPTO issued U.S. Patent No. 11,617,793 (the "US '793 Patent") that covers the PEDMARK® pharmaceutical formulation. The USPTO has also issued U.S. Patent No. 11,964,018 (the "US '018 Patent") (issued April 23, 2024), U.S. Patent No. 11,992,530 (the "US '530 Patent") (issued May 28, 2024), and U.S. Patent No. 11,998,604 (the "US '604 Patent") (issued June 4, 2024), which cover the use of PEDMARK® pharmaceutical formulations for reducing ototoxicity in a pediatric patient receiving cisplatin for the treatment of a localized cancer. Each of these patents has been listed in the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). 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 own one granted (US ‘026 Patent) and four additional pending US patent applications directed to additional sodium thiosulfate pharmaceutical formulations and methods of treatment using such formulations. These patents, if 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.

On October 29, 2021, Hope Medical Enterprises, Inc. (“Hope”) filed a Petition for inter partes review (IPR2022-00125) to invalidate our wholly owned U.S. Patent No. 10,792,363 (the “US ‘363 Patent”), which relates to an anhydrous form of STS and its method of manufacture, which is the active pharmaceutical ingredient in the PEDMARK® product. The US ‘363 Patent was issued October 6, 2020. During the US ‘363 Patent IPR, we disclaimed the patent claims directed to the anhydrous morphic form of STS and continued with claims directed to its method of manufacture. The validity of this method of manufacturing claims was affirmed by the PTAB in a Written Decision in favor of Fennec in September 2023.

U.S. Patent No. 10,596,190 (the “US ‘190 Patent”), in-licensed from Oregon Health and Sciences University, was previously listed in the Orange Book. On April 18, 2023, the PTAB invalidated the only claim of the US ‘190 Patent. The final written decision became effective June 20, 2023. In light of PTAB’s final written decision on the invalidity of the US ‘190 Patent, we requested that the FDA remove the US ‘190 Patent from the Orange Book.

We plan to vigorously defend our intellectual property rights to PEDMARK® if challenged. An invalidation of our patents covering PEDMARK® could have a material adverse effect on our ability to protect our rights in PEDMARK® beyond periods of marketing exclusivity for PEDMARK® in the United States under Orphan Drug Designation.

Orphan Drug Exclusivity and European Union Pediatric-Use marketing 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).

Following the approval of PEDMARQSI® (EU Brand name for PEDMARK®) in Europe on May 26, 2023, we were granted PUMA in the European Union pursuant to Regulation (EC) No. 1901/2006 and Regulation (EC) No. 1902/2006, which provides for 10 years of exclusivity (8 years of data exclusivity + 2 years of market exclusivity). This exclusivity is effective until May 26, 2033.

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

Under the Food, Drug, and 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, which is September 20, 2029.

On January 10, 2023, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:23-cv-00123), for infringement of the US ‘190 Patent, the US ‘728 Patent, and the US ‘984 Patent. On

April 20, 2023, we filed an Amended Complaint to assert infringement of the US '728 Patent and the US '984 Patent. On April 4, 2023, we were granted US 11,617,793 Patent (the "US '793 Patent") covering the formulation of the PEDMARK® product, which was listed in the Orange Book on or around April 17, 2023, and has an expiration date of July 2039. On May 11, 2023, we received written notice of CIPLA's Paragraph IV Certification as to the US '793 Patent, which was dated May 10, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the US '793 Patent is invalid, unenforceable, and/or will not be infringed by CIPLA's ANDA Product. On July 27, 2023, we filed a Second Amended Complaint to assert the US '793 Patent. CIPLA filed an Answer to the Second Amended Complaint on August 31, 2023.

On April 23, 2024, we were granted US 11,964,018 Patent (the "US '018 Patent) covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around May 8, 2024, and has an expiration date of July 2039. On May 28, 2024, we were granted US 11,992,530 Patent (the "US '530 Patent") covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 20, 2024, and has an expiration date of July 2039. On June 4, 2024, we were granted US 11,998,604 Patent (the "US '604 Patent") covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 24, 2024, and has an expiration date of July 2039.

On June 13, 2024, we filed a Motion for Leave to File a Third Amended Complaint to focus the ANDA litigation against CIPLA on the US '018 Patent and the US '793 Patent only. The non-asserted patents remain listed in the Orange Book. On July 22, 2024, CIPLA filed a response indicating that they do not oppose our Motion for Leave to File a Third Amended Complaint. On July 30, 2024, the court granted us leave to file the Third Amended Complaint, which we filed on September 16, 2024.

In coordination with the Third Amended Complaint, we entered into a covenant not to sue CIPLA on the US '363 Patent, US '728 Patent, US '984 Patent, US '530 Patent, and US '604 Patent, subject to the limitation that such shall not apply to the extent CIPLA alters the product or formulation described in its FDA ANDA application.

On May 27, 2025, we were granted US 12,311,026 (the "US '026 Patent") covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '026 Patent has an expiration date of July 2039.

On May 27, 2025, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:25-cv-05709), for infringement of the US '026 Patent based on the Cipla entities' ANDA filing. Subsequently, we filed a Motion to Consolidate Case No. 2:25-cv-05709 and Case No. 2:23-cv-00123.

On July 14, 2025, the court granted the Motion to Consolidate Case No. 2:25-cv-05709 with Case No. 2:23-cv-00123.
On July 14, 2025, the court issued its Order on Claim Construction on two claim terms in dispute in the '793 Patent and '018 Patent, adopting our proposed constructions for both.

On August 25, 2025, the CIPLA entities filed an Answer and Counterclaims to the complaint, alleging that the '026 Patent was invalid, not infringed, and/or unenforceable.

On September 18, 2025, we filed an Answer to CIPLA's Counterclaims.

On March 16, 2026, Fennec announced that it has entered into an agreement with Cipla Limited and Cipla USA, Inc. to settle the litigation between them regarding Cipla's application to FDA for approval to market a generic version of Fennec's PEDMARK® (sodium thiosulfate injection) product. See Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the agreement, the lawsuit will be dismissed with each party bearing their own costs, and Cipla will not enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain circumstances.

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 a third-party contract manufacturer to manufacture 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 the FDA's 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.

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 completed a Phase1b trial by Decibel Therapeutics with future development unclear. 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.

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

- our ability to maintain regulatory approvals for PEDMARK®in the U.S., EU and other global markets;
- our ability to obtain regulatory approvals for PEDMARK®in target markets outside of the U.S., EU and other global markets;

- the demonstrated efficacy, safety and reliability of our drug candidate;
- 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 U.S. and Canada and may require us to perform additional preclinical or clinical testing regardless of whether FDA or TPD 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 of 1983, 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 eight years of data protection plus two years of 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 a New Drug Application ("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 Orange Book. Drugs listed in the FDA Orange Book can, in turn, be cited by potential generic competitors in support of approval of an 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 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 FDA 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 FDA 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 FDA 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 2025, the application fee is $321,920 per ANDA application, and the facility fees are $231,952 per domestic finished dosage form facility, $246,952 per foreign finished dosage form facility, $41,580 per domestic active pharmaceutical ingredient facility, and $56,580 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 Designation and 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 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 plus two additional years of marketing exclusivity.

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 was 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 for employees 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 patients with rare, oncology related and orphan diseases and who are willing to work hard and in a collaborative manner to further that mission.

Employee Profile

As of December 31, 2025, we had approximately 35 employees, 19 of whom are in our commercial 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 historically had 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 $250 and $310 for the fiscal years ended December 31, 2025 and 2024, 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 globally. 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 will be ineffective or toxic, or will otherwise fail to receive or, where received, maintain 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 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 future development of PEDMARK®.

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. and Fennec Limited 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.

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 $9,741 for the year ended December 31, 2025 and reported a net loss of approximately $436 for the year ended December 31, 2024. At December 31, 2025, we had an accumulated deficit of approximately $229,422. We anticipate potentially incurring substantial additional losses due to the need to spend significant amounts on activities required for the continued commercialization of PEDMARK in the U.S. and for obtaining and maintaining regulatory approvals for PEDMARK outside of the U.S., as well as for 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®. PEDMARQSI® has also been approved in the EU and U.K. We anticipate potential substantial regulatory review prior to the commercialization of PEDMARK® outside of the United States, E.U. and U.K. We anticipate substantial regulatory review prior to the commercialization of PEDMARK® outside of the United States. Any disruption in manufacturing, supply, reimbursement, or adoption, or any adverse regulatory or competitive development, could materially harm our business.

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 $36.8 million available as of December 31, 2025 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, E.U. and U.K. 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.

Regulatory approval for any approved product is limited by the FDA and foreign regulatory authorities to those specific indications and conditions for which clinical safety and efficacy have been demonstrated as set forth on the product label. If we market PEDMARK® for uses beyond such approved indications, we could be subject to enforcement action, which could have a material adverse effect on our business.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. If we are not able to obtain FDA approval for any desired future indications for PEDMARK®, our ability to effectively market and sell PEDMARK® may be reduced and our business may be adversely affected.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote PEDMARK® is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Further, the National Comprehensive Cancer Network ("NCCN") guideline recommendations include patient populations and settings that may extend beyond PEDMARK's current FDA-approved label. Regulatory scrutiny regarding promotion, changes to guidelines, or payer coverage limitations for off-label uses could adversely affect demand and expose us to compliance risk.

International commercialization of PEDMARK® requires successful partnerships.

Our international commercialization strategy depends on collaborative relationships with our third party development partners, including Norgine in Europe and other development partners or distributors in additional territories. We have limited foreign regulatory, clinical and commercial resources. Future partners are critical to our international success. We may not be able to enter into collaboration agreements with appropriate partners for important foreign markets on acceptable terms, or at all. Future collaborations with foreign development partners may not be effective or profitable for us. We will need to obtain approval from the appropriate regulatory, pricing and reimbursement authorities to market PEDMARK® internationally, and we may be unable to obtain foreign regulatory approvals. Pursuing foreign regulatory approvals will be time-consuming and expensive. The regulations can vary among countries and foreign regulatory authorities may require different or additional clinical trials than we conducted to obtain FDA approval for PEDMARK®. If our foreign development partners fail to execute effectively, we may not realize anticipated milestone payments, royalties, or meaningful revenue outside of the United States.

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 become 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 Fennec HEARS® 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 research and development collaboration arrangements with academic institutions and other third-party collaborators.

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. 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 in the U.S. and abroad.

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 complete response letters ("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 six 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® have been granted in the United States under orphan drug exclusivity 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 concluded litigation against CIPLA, as described elsewhere in this Annual Report. On March 16, 2026, Fennec announced that it has entered into an agreement with Cipla Limited and Cipla USA, Inc. to settle the litigation between them regarding Cipla's application to FDA for approval to market a generic version of Fennec's PEDMARK® (sodium thiosulfate injection) product. *See Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc*., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the agreement, the lawsuit will be dismissed with each party bearing their own costs, and Cipla will not enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain circumstances. 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.

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 manufactured 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.

Geopolitical instability and armed conflicts in Turkey and the Middle East could disrupt our product distribution and sales and adversely affect our business.

We depend on third-party logistics providers, distributors, and healthcare systems to store, transport, and dispense our products in Turkey and the broader Middle East region. Geopolitical instability, regional tensions, and armed conflicts in these markets may disrupt shipping lanes and border crossings, increase freight, insurance, and security costs, or otherwise delay or prevent delivery of our products to patients, as well as negatively affect prescribing, reimbursement, and demand, any of which could materially and adversely affect our business, results of operations, and financial condition.

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 have been in the past 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 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 2021 announcement that we expected to receive another CRL from the FDA regarding our NDA for PEDMARK®. Both of these cases have been dismissed and closed. 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 and in the European Commission in June 2023 of PEDMARQSI®, 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. During 2025, we delivered sequential quarterly revenue growth and achieved positive operating cash flow in the third quarter of 2025; however, we may not be able to sustain this trajectory and our future results will depend on continued adoption, payer access, and disciplined cost management.

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. 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 in circumstances where the officer or director did not act honestly and in good faith with a view to the best interests of the company or the associated corporation, as the case may be, or in the case of a proceeding other than a civil proceeding, if the officer or director did not have reasonable grounds for believing that the eligible party's conduct in respect of which the proceeding was brought was lawful), 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 articles 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. We believe 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, like the recent COVID-19 pandemic.

Future health epidemics may affect 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 rising 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.

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 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 product. 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 drug product, 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.

We have entered into, and may in the future enter into, strategic transactions for the research, development and commercialization of PEDMARK. If any of these transactions are not successful, then we may not be able to capitalize on the market potential of such product. Further, we may not be able to enter into future transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize our potential future product candidates and former lead product candidate, impact our cash position, increase our expense, and present significant distractions to our management.

We have entered into, and may enter into in the future, strategic transactions, such as out-licensing of our product or technologies. For example, in March 2024, we entered into a collaboration and license agreement with Norgine. Our ability to generate revenue from any of our strategic transactions will depend on our partners' abilities to successfully perform the functions assigned to them in these transactions. We cannot predict the success of any of our strategic transactions.

We also intend to evaluate and, if strategically attractive, seek to enter into additional collaborations in the future, including with biotechnology or biopharmaceutical companies or hospitals. The competition for partners is intense, and the negotiation process is time-consuming and complex. If we are not able to enter into strategic transactions, we may not have access to required liquidity or expertise to further develop our potential future product candidates or our discovery platform.

Any existing or potential future collaboration or other strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of such acquisitions or collaborations. In addition, any new collaboration that we enter into may be on terms that are not optimal for us.

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 and in the European Commission, and we cannot guarantee that we will ever have regulatory approval outside the United States and European Commission. 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. In June 2023, we obtained approval for PEDMARQSI® in the European Union and in October 2023 in the U.K.

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 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 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, European Union 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.

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 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, President Trump, in his first term, 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, the President 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.

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.

Our reliance on global distributors exposes us to risks related to nonperformance of key services, uncertainty of cash flow timing, and nonpayment for delivered goods.

We depend on third-party distributors to commercialize and deliver our product in various global markets. These distributors may experience operational or financial difficulties that could result in disruptions to our supply chain, delays in product delivery, or failure to meet contractual obligations. In addition, the timing of payments from these distributors may be inconsistent, creating uncertainty in our cash flow projections and financial planning. There is also a risk that some distributors may be unable or unwilling to pay for delivered goods due to financial distress or disputes, which could result in significant losses. If our distributors fail to perform, it may have a material adverse effect on our revenue, profitability, and ability to achieve our business objectives.

Risks Related to Our Intellectual Property

Our commercial success will rely upon the strength of our patents to exclude competition.

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 product 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. 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 section entitled "Item 1. Business– Intellectual Property," we received a letter dated November 30, 2022, notifying us that 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 the US '190 patent, expiration date January 2038; and the US '728 patent, expiration date July 2039. We received a letter dated January 5, 2023, notifying us that CIPLA submitted to the FDA a Paragraph IV Certification on the US '984 patent. These patents are listed in the FDA 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. On March 16, 2026, Fennec announced that it has entered into an agreement with Cipla Limited and Cipla USA, Inc. to settle the litigation between them regarding Cipla's application to FDA for approval to market a generic version of Fennec's PEDMARK® (sodium thiosulfate injection) product. *See Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc*., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the agreement, the lawsuit will be dismissed with each party bearing their own costs, and Cipla will not enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain circumstances.

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.

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 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. We filed a patent infringement lawsuit against CIPLA, and will continue to 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 17, 2026, 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 17, 2026, 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, 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 17, 2026, our current shareholders separately representing more than 5% ownership of our common shares collectively represented beneficial ownership of approximately 41% of our common shares. In particular, Essetifin SpA, owns approximately 4.0 million shares, or approximately 11.6% of our issued and outstanding common shares, Rosalind Advisors Inc. reported beneficial ownership of 2.7 million shares, or approximately 8.0% of our outstanding common shares, Southpoint Capital Advisors LP ("Southpoint Capital") owns or exercises control over approximately 2.7 million

shares, representing approximately 8.0% of our issued and outstanding common shares; Sonic Fund II, LP, owns approximately 2.6 million shares, or approximately 7.6% of our issued and outstanding common shares; 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 17, 2026, we had 0.1 million warrants outstanding to purchase 0.1 million shares of our common shares at an exercise price of $8.11 per common share. In addition, as of March 17, 2026, there were approximately 5.9 million common shares issuable upon the exercise of outstanding stock options with a weighted average exercise price of $6.38 per common share. We may also issue further warrants as part of any future financings in addition to the additional 0.7 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, 2025. 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.

Risks Related to Information Technology

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, trade secrets and any other sensitive data.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by Artificial Intelligence, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation clinical trial data processing, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate such vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including affected individuals, customers, regulators, and investors. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management's attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable laws and regulations. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We, through our third-party service provider that manages our information technology systems and networks, have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

Our security policies and processes are based on industry best practices and are revisited regularly to ensure their appropriateness based on risk, threats and current technological capabilities. We regularly assess our threat landscape and monitor our systems and other technical security controls, maintain information security policies and procedures, including a breach response plan, ensure maintenance of backup and protective systems, and engage with a Managed Service Provider who has a team of security personnel managing our efforts and initiatives. We review System and Organization Controls 1 (SOC 1 Type II) certifications where relevant from key third party partners and other service providers with access to information assets at least annually.

We maintain Information Systems Incident Management Standards that are intended to ensure information security events and weaknesses associated with information systems are communicated and acted on in a timely manner. Our internal controls and procedures address cybersecurity and include processes intended to ensure that security breaches are reported to appropriate personnel and, if warranted, analyzed for potential disclosure. While we have experienced cybersecurity attacks, such attacks to date have not materially affected the Company or our business strategy, results of operations, or financial condition.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- designated team members are responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- Maintain insurance coverage that is intended to address certain aspects of cybersecurity risks.

To date, there have not been any cybersecurity threats that have materially affected the Company.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and oversees our cybersecurity and other information technology risks and management's implementation of our cybersecurity risk management program.

Our Board receives periodic reports from management on our cybersecurity risks. In addition, management updates the Board and the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

Our management team, including our Chief Financial Officer, is responsible for assessing and managing our material risks from cybersecurity threats. Our Chief Financial Officer has primary responsibility for our overall cybersecurity risk management program and supervises our retained provider of IT services and external cybersecurity consultants. Our Chief Financial Officer has experience supervising and managing company security and privacy departments.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from external security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

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.

On August 1, 2023, the Company entered into a second Office Service Agreement (the "Second Office Service Agreement") with Regus to lease office space in Dublin, Ireland. Per the terms of the Second Office Service Agreement, the monthly rent payments are €2,000. The Company was required to pay a security deposit of €4,000, which is the equivalent of two months rent. The Second Office Service Agreement commenced on August 1, 2023 and terminates on January 31, 2025, thereafter the lease may continue on a month-to-month basis with either party being able to terminate the agreement by providing one months' advance written notice of termination. This office agreement terminated on January 31, 2025.

Item 3. Legal Proceedings

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

Under the Food, Drug, and 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, which is September 20, 2029.

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

Amended Complaint to assert the US '793 Patent. CIPLA filed an Answer to the Second Amended Complaint on August 31, 2023.

On April 23, 2024, we were granted US 11,964,018 Patent (the "US '018 Patent) covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around May 8, 2024, and has an expiration date of July 2039. On May 28, 2024, we were granted US 11,992,530 Patent (the "US '530 Patent") covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 20, 2024, and has an expiration date of July 2039. On June 4, 2024, we were granted US 11,998,604 Patent (the "US '604 Patent") covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 24, 2024, and has an expiration date of July 2039.

On June 13, 2024, we filed a Motion for Leave to File a Third Amended Complaint to focus the ANDA litigation against CIPLA on the US '018 Patent and the US '793 Patent only. The non-asserted patents remain listed in the Orange Book. On July 22, 2024, CIPLA filed a response indicating that they do not oppose our Motion for Leave to File a Third Amended Complaint. On July 30, 2024, the court granted us leave to file the Third Amended Complaint, which we filed on September 16, 2024.

In coordination with the Third Amended Complaint, we entered into a covenant not to sue CIPLA on the US '363 Patent, US '728 Patent, US '984 Patent, US '530 Patent, and US '604 Patent, subject to the limitation that such shall not apply to the extent CIPLA alters the product or formulation described in its FDA ANDA application.

On May 27, 2025, we were granted US 12,311,026 (the "US '026 Patent") covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '026 Patent has an expiration date of July 2039.

On May 27, 2025, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:25-cv-05709), for infringement of the US '026 Patent based on the Cipla entities' ANDA filing. Subsequently, we filed a Motion to Consolidate Case No. 2:25-cv-05709 and Case No. 2:23-cv-00123.

On July 14, 2025, the court granted the Motion to Consolidate Case No. 2:25-cv-05709 with Case No. 2:23-cv-00123.
On July 14, 2025, the court issued its Order on Claim Construction on two claim terms in dispute in the '793 Patent and '018 Patent, adopting our proposed constructions for both.

On August 25, 2025, the CIPLA entities filed an Answer and Counterclaims to the complaint, alleging that the '026 Patent was invalid, not infringed, and/or unenforceable.

On September 18, 2025, we filed an Answer to CIPLA's Counterclaims.

On March 16, 2026, Fennec announced that it has entered into an agreement with Cipla Limited and Cipla USA, Inc. to settle the litigation between them regarding Cipla's application to FDA for approval to market a generic version of Fennec's PEDMARK® (sodium thiosulfate injection) product. *See Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc*., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the agreement, the lawsuit will be dismissed with each party bearing their own costs, and Cipla will not enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain circumstances.

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 17, 2026, 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 sections entitled "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A - Risk Factors" 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

Fennec Pharmaceuticals Inc., a corporation existing under the laws of British Columbia, was originally formed under the name Adherex Technologies Inc. and subsequently changed its name on September 3, 2014. Fennec is a commercial stage specialty pharmaceutical company dedicated to preventing cisplatin-induced ototoxicity ("CIO"), a serious and often irreversible side effect of cancer treatment, with one FDA approved and European Commission approved product, PEDMARK® in the U.S. and PEDMARQSI®, which is the branded name for PEDMARK® outside of the U.S. (collectively, "PEDMARK"), developed to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. The Company has four wholly owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian corporation, and Fennec Pharmaceuticals (EU) Limited, an Ireland company ("Fennec Limited"). With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive. On September 20, 2022, we received approval from the FDA for PEDMARK® (sodium thiosulfate injection). This approval makes PEDMARK® the first and only treatment approved by the FDA in this area of significant unmet medical need. On October 17, 2022, we announced commercial availability of PEDMARK® in the United States. Further, PEDMARQSI® received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

PEDMARK® is currently the 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. In clinical studies in this population, treatment with PEDMARK® resulted in an approximate 50% relative reduction in the incidence of cisplatin-induced hearing loss compared to cisplatin alone, without evidence of materially compromised antitumor efficacy. PEDMARK® is administered as a short intravenous infusion and has generally been associated with a mild-to-moderate and manageable safety profile consistent with its known pharmacology.

In March 2024, we announced that we entered into an agreement with Norgine, a leading European specialist pharmaceutical company. This is an exclusive licensing agreement under which Norgine will commercialize PEDMARQSI® in Europe, Australia and New Zealand. PEDMARQSI® is the first and only approved therapy in the EU and U.K. for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients one month to eighteen years of age with localized, non-metastatic solid tumors. During 2025, Norgine made PEDMARQSI® commercially available and expects additional launches to occur in 2026 and beyond.

Under the terms of the Norgine licensing agreement, Fennec received approximately $43 million in upfront consideration and may receive up to approximately $230 million in additional commercial and regulatory milestone payments and double-digit tiered royalties (up to the mid-twenties) on net sales of PEDMARQSI® in the licensed territories. To date, Fennec has not received any milestone payments. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

In the United States, we sell our product through an experienced field force including Regional Pediatric Oncology Specialists and we utilize medical science liaisons within our medical team who help educate the medical communities and patients about CIO 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 PEDMARK® 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 six patents listed for PEDMARK® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book"). In September 2022, the United States Patent and Trademark Office ("USPTO") issued Patent No. 11,291,728 (the "US '728 Patent"), in December 2022, the USPTO issued Patent No. 11,510,984 ("US '984 Patent") and in April 2023, the USPTO issued Patent No. 11,671,793 ("US '793 Patent") that covers PEDMARK® pharmaceutical formulation. Further, additional issued patents included US 11,964,018 Patent (the "US '018 Patent) and US 11,992,530 Patent (the "US '530 Patent") and US 11,998,604 Patent (the "US '604 Patent") covering methods of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '728, US '984, US '793, US '018, US '530, and US '604 Patents will expire in 2039. Additional patents covering PEDMARK® formulation have been granted in Australia, Canada, the European Patent Office (EPO) (described further below), Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, and Russia, and patent applications covering PEDMARK® are pending in Brazil, China, the European Patent Office (EPO), Hong Kong, Israel, Korea, Mexico, New Zealand, Singapore, and Thailand. Patents covering alternative sodium thiosulfate formulations have been granted in the United States (US 12,311,026 (the "US '026 Patent"), Canada, Korea, Mexico, and Russia, and patent applications covering alternative sodium thiosulfate formulations are pending in the United States, Australia, the EPO, Hong Kong, Indonesia, Japan, Malaysia, Mexico, and New Zealand. Applications from these patent families, where granted, valid, and enforceable, will expire in July 2039, exclusive of any patent term adjustment or extension

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® 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 cancer patients 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.

In the United States, PEDMARK® is the first and only therapy approved to mitigate the risk of ototoxicity associated with cisplatin in pediatric patients aged one month and older with localized, non-metastatic solid tumors. Further, the National Comprehensive Cancer Network (NCCN) recommended the use of PEDMARK® to reduce the risk of cisplatin-induced ototoxicity in patients with localized, non-metastatic solid tumors (category 2A) for Adolescent and Young Adult (AYA) Oncology. As of January 2025, all medical compendia have incorporated Fennec's clinical updates, and AHFS, the largest online platform for pharmacists, has updated its content to reflect and differentiate PEDMARK® in accordance with its labeling.

PEDMARK® is the first and only FDA- and EMA-approved agent designed to reduce the risk of CIO in pediatric patients with localized solid tumors. The strategic imperatives driving the execution of PEDMARK®'s strategy include increasing awareness of unmet patient needs and emphasizing the importance of preventing CIO among oncologists. A key goal is to establish PEDMARK® as the standard of care (SOC) for all CIO prevention. Additionally, efforts focus on expanding adoption beyond oncologists by ensuring healthcare providers (HCPs) gain confidence in and have positive experiences with PEDMARK®. Ensuring seamless access for advocacy groups, payers, and providers is also a priority, along with activating patients and caregivers through disease education to drive demand for PEDMARK®. Key activities supporting these objectives include an expanded sales team with a strong track record in both academic and community settings,

partnerships with group purchasing organizations, and specialty pharmacy offerings such as home infusions, white bag delivery, and direct billing. Furthermore, digital materials, a digital speaker bureau to engage pediatric oncologists, audiologists, nurses, and pharmacists, along with a patient access services hub and ongoing support from advocacy groups, are all integral components of the strategy.

In the U.S. and Europe, Fennec estimates that there are approximately 11,400 pediatric patients with localized, non-metastatic solid tumors each year, of which include approximately 2,157 cisplatin-treated pediatric patients in the U.S. and 1,250 in Europe who fall within the current PEDMARK® market. The incidence and severity of CIO depends on the cumulative dose and duration of chemotherapy. Many affected children ultimately require hearing aids or, in more severe cases, cochlear implants, which are costly, technically complex and do not fully restore normal hearing. PEDMARK® is the first and only therapy approved in the U.S. to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. Infants and young children who experience ototoxicity during critical developmental windows are at risk for impaired speech and language development and literacy, while older children and adolescents may face long-term challenges in academic performance, social-emotional development, career potential and independent living.

In the U.S., approximately 90% of pediatric cancer patients receive care at approximately 200 key pediatric hospital centers, including institutions within the Children's Oncology Group (COG), National Cancer Institute (NCI) and National Comprehensive Cancer Network (NCCN).

The Adolescent and Young Adult ("AYA") oncology patient is defined as an individual between 15 and 39 years of age at the time of initial cancer diagnosis. In the U.S., Fennec estimates that there are approximately 51,282 new AYA solid tumor cases annually, of which approximately 25,536 involve cisplatin-treated patients with localized, non-metastatic solid tumors. The most common relevant tumor types include germ cell tumors, testicular cancer, thyroid cancer and breast cancer. The U.S. AYA oncology treatment landscape spans both academic and community settings, with 72 NCI-designated academic centers treating roughly 20% of AYA oncology patients, while approximately 80% are managed across approximately 3,750 community oncology centers nationwide.

CIO and Unmet Medical Need

Cisplatin is a cornerstone of modern cancer therapy for many pediatric and AYA solid tumors, with reported overall survival rates in some cisplatin-treated cancers exceeding 80%. However, cisplatin is associated with a high incidence of ototoxicity. Published data indicates that approximately 60% to 90% of cisplatin-treated patients may develop some degree of permanent, sensorineural hearing loss, with reported rates of 40% to 80% occurring in adults and 50% to 90% in children. CIO typically begins as bilateral, high-frequency hearing loss that is progressive and irreversible, occasionally accompanied by tinnitus. In some cases, it may ultimately require the use of hearing aids or cochlear implants.

Published literature has linked treatment-related hearing loss to impairments in speech and language development, reduced academic performance, challenges in social-emotional development, and enduring impacts on educational attainment, vocational opportunities, and independent living. Additionally, published research indicates that severe to profound early-onset hearing loss can impose a substantial lifetime economic burden, with per-individual costs estimated at approximately $489 and potentially exceeding $1,000 on an undiscounted basis, primarily due to lost productivity, educational expenses, and medical costs. These figures are derived from published literature regarding the disease burden of hearing loss and do not represent demonstrated health-economic outcomes specifically attributable to PEDMARK.

European Commission Marketing Authorization

PEDMARQSI® (PEDMARK® brand name in Europe) received European Commission Marketing Authorization in June 2023 and received U.K. approval in October 2023.

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

Under the terms of the licensing agreement, Fennec received approximately $43 million in upfront consideration and may receive up to approximately $230 million in additional commercial and regulatory milestone payments and double-digit tiered royalties on net sales of PEDMARQSI® in the licensed territories up to the mid-twenties. To date, Fennec has not received any milestone payments. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

In December 2024, PEDMARQSI® received positive final draft guidance from the National Institute for Health and Care Excellence (NICE). Most recently, in 2025, Norgine launched PEDMARQSI® in Germany and the U.K

Distribution Agreement – Turkey and the Gulf Cooperation Council

In 2025, we entered into a distribution agreement with Inpharmus for the commercialization of PEDMARK® in Turkey and the GCC countries. Under this agreement, Inpharmus will be responsible for certain regulatory, commercialization and distribution activities in the covered territories, and we will supply PEDMARK® and receive payments, subject to specified terms and conditions. Commercialization in these markets is subject to obtaining and maintaining necessary regulatory approvals and reimbursement, and there can be no assurance as to the timing or magnitude of future revenues, if any, from these territories.

Japan: STS-J01 Investigator-Initiated Trial and Registration Plans

In Japan, an independent investigator-initiated clinical trial, known as STS-J01, has been evaluating PEDMARK® for the prevention of CIO. In December 2025, we announced positive topline results from this trial that demonstrated use of PEDMARK® was associated with a significant reduction in the incidence of hearing loss compared to historically reported rates in patients receiving cisplatin alone, with no evidence of reduced antitumor activity and an approximate 95% clinical response rate. Based on these results, we are pursuing a regulatory registration strategy for PEDMARK® in Japan and are evaluating partnering or licensing opportunities in that market, similar to our model with Norgine in Europe. Any such registration and partnering activities will be subject to applicable regulatory requirements and successful negotiations with potential partners.

Investigator-Initiated Studies and Lifecycle Management

In addition to our pivotal pediatric studies (SIOPEL6 and COG ACCL0431), we support a number of investigator-initiated and other clinical studies designed to further characterize the use of PEDMARK® in additional tumor types and patient populations. For example, City of Hope, a U.S. cancer research and treatment organization, is conducting an investigator-initiated clinical trial evaluating PEDMARK® in adult men with stage II–III metastatic testicular germ cell tumors receiving cisplatin-based chemotherapy. We also engage in medical affairs activities and data-generation initiatives to expand the clinical evidence base for PEDMARK®, including in AYA and adult populations. These studies are exploratory in nature, and PEDMARK® is not currently approved for use in metastatic cancers or adult populations outside of its labeled indication. Any potential label expansion will require additional clinical data and regulatory approvals.

Commercial Infrastructure and Patient Support Programs

During 2025, we significantly expanded our commercial infrastructure and patient support capabilities. Our Fennec HEARS® program provides comprehensive education, access, and reimbursement assistance to patients and healthcare providers. The program includes:

- Financial support: A $0 copay savings program for eligible patients with commercial or private insurance and the Fennec Patient Assistance Program for eligible patients without insurance.
- Patient and product support: Dedicated care coordinators to answer insurance questions, assist with prior authorizations, and provide treatment resources.
- Distribution network: Established third-party logistics providers (3PL) and specialty pharmacy partnerships with home infusion support capabilities.
- Provider engagement: Peer-to-peer speaker bureau, medical science liaison (MSL) team, and comprehensive marketing initiatives across multiple channels.

We have achieved formulary adoption at certain large oncology networks and academic institutions, with successful activations in both academic centers and community oncology practices occurring throughout 2025.

Results of Operations

Fiscal 2025 versus Fiscal 2024

In thousands of U.S. Dollars	Fiscal Year Ended December 31, 2025	%	Fiscal Year Ended December 31, 2024	%	Increase (Decrease)
Product sales, net	$ 44,642		$ 29,580		$ 15,062
Licensing revenue	—		17,958		(17,958)
Total revenue	44,642		47,538		(2,896)
Operating expenses:					
Cost of product sales	3,764	7 %	3,184	7 %	580
Research and development	250	0 %	307	1 %	(57)
Selling and marketing	18,616	37 %	18,426	41 %	190
General and administrative	28,294	56 %	23,053	51 %	5,241
Total operating expense	50,924	100 %	44,970	100 %	5,954
(Loss)/Income from operations	(6,282)		2,568		(8,850)
Unrealized loss on securities	(2)		(81)		79
Amortization expense	(64)		(89)		25
Interest expense	(2,080)		(4,069)		1,989
Unrealized foreign exchange gain/(loss)	28		(82)		110
Loss on debt extinguishment	(2,022)		—		(2,022)
Interest income	787		1,682		(895)
Loss before income tax	(9,635)		(71)		(9,564)
Income tax	(106)		(365)		259
Net loss	**$ (9,741)**		**$ (436)**		**$ (9,305)**

- The Company recorded net product sales of $44,642 in fiscal 2025 compared to $29,580 in fiscal 2024, reflecting increased market penetration and expanded access for PEDMARK®, including continued expansion of the Company's focus on the AYA population. Total revenue decreased to $44,642 in fiscal 2025 from $47,538 in fiscal 2024, primarily due to the absence of $17,958 of licensing revenue recorded in fiscal 2024 related to the Norgine transaction, partially offset by higher net product sales in 2025. The Company recorded discounts and allowances against sales of $9,165 and cost of product sales of approximately $3,764 during fiscal year 2025, consistent with higher commercial volumes and expanded payer mix.

- Research and development expense decreased by approximately $57 in fiscal 2025 compared to fiscal 2024, reflecting lower overall development spending, partially offset by increasing costs associated with investigator-initiated clinical trials supporting PEDMARK® and potential lifecycle expansion opportunities.

- Selling and marketing expenses increased modestly to $18,616 in fiscal 2025 from $18,426 in fiscal 2024, driven primarily by higher payroll-related costs, expanded commercial field activities, and increased marketing expenditures as the Company continued to broaden outreach to community oncology centers and expand its focus on the AYA population offset by a decrease in pre commercial activities related to Europe which occurred in 2024.

- General and administrative expenses increased by $5,241 in fiscal 2025 compared to fiscal 2024, primarily due to higher consulting and professional fees, and increased equity remuneration.

- Amortization expense decreased by approximately $25 in fiscal 2025 compared to fiscal 2024, primarily due to the continued amortization of deferred financing costs.

- Interest expense decreased by approximately $1,989 in fiscal 2025 compared to fiscal 2024, primarily due to lower average outstanding debt balances and the impact of debt repayments during the year. Interest expense is expected to decline to zero after the full debt paydown in November 2025. Fiscal 2025 interest expense also decreased due to the early repayment of debt.

- Interest income decreased by approximately $895 in fiscal 2025 compared to fiscal 2024, primarily due to lower average invested cash balances during the year and lower yields on money market investments.

- Income tax expense decreased to $106 in fiscal 2025 compared to $365 in fiscal 2024, as the prior-year amount primarily reflected income tax expense related to taxable income generated from the Norgine licensing transaction, with less comparable taxable income recorded in fiscal 2025.

Selected Asset and Liability Data (thousands):	As at December 31, 2025	As at December 31, 2024
Cash and equivalents	$ 36,788	$ 26,634
Other current assets	30,255	17,490
Current liabilities	10,518	6,919
Working capital [1]	56,525	37,205
[1] [Current assets – current liabilities]		
Selected Equity:		
Common stock and additional paid in capital	263,651	212,566
Accumulated deficit	(229,422)	(219,681)
Shareholders' equity/(deficit)	35,472	(5,872)

- There was a $10,154 net increase in cash and cash equivalents between December 31, 2025 and December 31, 2024, increasing to $36,788 at December 31, 2025 from $26,634 at December 31, 2024. The increase was primarily driven by cash inflows from net product sales, proceeds from equity issuances and option exercises, and improved operating cash flow, $42,000 of net proceeds from our November 2025 public equity offering and concurrent Canadian private placement, partially offset by $21,729 paid toward the Petrichor Financing note, ongoing operating expenditures related to the commercialization of PEDMARK, and other working capital uses.

- Other current assets increased by $12,765 between December 31, 2025 and December 31, 2024, primarily due to an increase in accounts receivable associated with higher product sales volumes, an increase in prepaid expenses and other current assets, and changes in inventory balances as the Company scaled commercial operations.

- Current liabilities increased by $3,599 at December 31, 2025 compared to December 31, 2024, primarily reflecting higher accrued expenses and other current liabilities associated with increased commercial activity and operating scale, partially offset by reductions in debt-related current obligations following repayments during the year.

- Working capital increased by $19,320 between December 31, 2025 and December 31, 2024, primarily as a result of higher cash balances, increased accounts receivable from higher product sales, partially offset by increased current liabilities and cash used in operations related to the continued commercialization of PEDMARK and the repayment of the Petrichor Financing note.

Selected Cash Flow Data (dollars and shares in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024
Net cash (used in)/provided by operating activities	$ (12,473)	$ 26,980
Net cash provided by investing activities	—	—
Net cash provided by /(used in) financing activities	22,627	(13,615)
Net cash flow	$ 10,154	$ 13,365

Net cash used in operating activities for the year ended December 31, 2025 was approximately $12,473, compared to net cash provided by operating activities of $26,980 for the year ended December 31, 2024. The decrease in operating cash flows was primarily attributable to the 2024 benefit from the licensing of the Norgine transaction, changes in working capital, including increases in accounts receivable and inventory and increases in accrued liabilities and other operating liabilities, partially offset by non-cash expenses such as stock-based compensation and amortization.

Net cash provided by financing activities for the year ended December 31, 2025 was approximately $22,627, compared to net cash used in financing activities of $13,615 for the year ended December 31, 2024. Cash provided by financing activities in 2025 was primarily attributable to net proceeds from equity financings, partially offset by repayments under the Company's debt arrangements, including amounts due under the Petrichor agreement, and lower proceeds from stock option exercises. Cash used in financing activities in 2024 primarily reflected repayments of debt and related fees, partially offset by proceeds from stock option exercises.

Net cash increased by approximately $10,154 during the year ended December 31, 2025, compared to an increase of approximately $13,365 during the year ended December 31, 2024.

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 $36,788 as of December 31, 2025. We currently anticipate that our available capital resources, including our existing cash and cash equivalents and the accounts receivable balances 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, 2025, we had approximately $36,788 in our cash accounts and $33,716 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.

On November 17, 2025, we completed an underwritten public offering of 5,367 of our common shares (including 700 common shares issued upon the underwriters' full exercise of their option to purchase additional shares) at a public offering price of $7.50 per share, for gross proceeds of approximately $40.25 million, before deducting underwriting discounts and offering expenses. Concurrently with the public offering in the United States, we completed a non-brokered private offering of our common shares in Canada to certain existing institutional shareholders at a price of $7.50 per share, for aggregate gross proceeds of approximately $5.025 million, before offering expenses.

We used a substantial portion of the net proceeds from the offering to redeem our outstanding debt obligations. The remaining net proceeds are intended to be used for working capital and other general corporate purposes.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

None, other than the severance amounts described in notes to our consolidated financial statements contained elsewhere in this Annual Report.

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, 2025 consolidated financial statements.

Credit Losses

The Company estimates and records a provision for its expected credit losses related to its trade receivables. The Company considers historical collection rates, the current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses. However, because of the short time to the expected receipt of accounts receivable, the Company believes that the carrying value, net of excepted losses, approximates fair value and therefore, relies more on historical and current analysis of its trade receivables.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer, as the Company determined that risk profile of its customers may vary based on certain characteristics such as credit history, past payment history and geography. Each class of customer component is analyzed for estimated credit losses individually. In doing so, the Company establishes a customer profile, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the life sciences industry to estimate if there are current expected credit losses within its trade receivables based on the trends and the Company's expectation of the future status of such economic and industry-specific factors. Also, specific allowance amounts are established based on review of outstanding invoices to record the appropriate provision for customers that have a higher probability of default.

In addition to the quantitative information disclosed in Note 2, the allowance for credit losses on trade receivables is closely linked to the estimates and assumptions that underlie our gross-to-net deductions, including expected chargebacks,

rebates, co-pay assistance and other commercial and government discounts. Changes in payer mix and utilization trends could result in meaningful increases or decreases in the allowance for credit losses and related expense in future periods.

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.

Product Sales Discounts and Allowances

The Company records U.S. based 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.

The Company also utilizes select distributors to introduce its product into global markets. These distributors take on the function of shipping, storage, marketing and other services related to the sale of our product. We record distribution and other fees paid to these distributors as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services received. If both conditions are met, we record the consideration paid to the distributor as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

License Agreements

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

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

performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as separate performance obligations.

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

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

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, 2025 and 2024, we used the following weighted average assumptions:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
Expected dividend	—	%	—	%
Risk-free interest rate	3.83 - 4.19	%	3.64 - 5.15	%
Expected volatility	71.04 - 161.67	%	55.00 - 162.00	%
Expected life	1.5 - 6.0 years		1.5 - 6.0 years	

Performance-based units

For performance share units, the Company also makes significant estimates regarding the probability of achieving specified revenue-based performance milestones and recognizes compensation expense based on the grant-date fair value of the awards over the applicable performance period. The revenue performance milestones for the PSU awards granted in 2025 were achieved during the year, and the related compensation cost has been fully recognized as of December 31, 2025.

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, 2025 and December 31, 2024 are as follows (in thousands):

Outstanding Share Type	December 31, 2025	December 31, 2024	Change
Common shares	34,163	27,527	6,636
Warrants	111	150	(39)
Stock options	5,853	5,855	(2)
Total	40,127	33,532	6,595

Newly Adopted and Recent Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. This guidance will be effective for the annual periods beginning the year ended December 31, 2025. The Company adopted ASU 2023-09 on January 1, 2025, on a prospective basis, and the adoption affected only the Company's income tax disclosures and did not have an impact on its consolidated results of operations, financial position or cash flows.

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure of additional disaggregated information about significant expenses within relevant income statement captions, such as purchases of inventory, employee compensation, depreciation, amortization and depletion. The new guidance is effective for annual periods beginning after December 15, 2026, and interim periods within annual periods beginning after December 15, 2027. We are currently evaluating the impact of this standard on our consolidated financial statements.

In July 2025, the FASB issued ASU No. 2025-05, "Measurement of Credit Losses for Accounts Receivable and Contract Assets" ("ASU 2025-05"). The guidance in ASU 2025-05 amends ASC Topic 326, Financial Instruments-Credit Losses, to provide a practical expedient to simplify estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC Topic 606, Revenue from Contracts with Customers. The practical expedient, if elected, allows entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. The standard is effective for annual fiscal years beginning after December 15, 2025 and interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. Entities that elect the practical expedient should apply the guidance prospectively. The Company is currently evaluating the impact that the adoption of ASU 2025-05 may have on its 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 mortgage-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, 2025, we had $33,716 in money market investments and savings accounts as compared to $24,614 at December 31, 2024; 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, 2025 and 2024; however, the amounts we hold in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

Our investment policy is to manage investments to achieve, in the order of importance, the financial objectives of preservation of principal, liquidity and return on investment. 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 and Euros. To date, we have not employed the use of derivative instruments; however, we do hold Canadian dollars and Euros which we use to pay vendors in Canada and the EU in addition to other corporate obligations. At December 31, 2025, we held approximately CAD$210 and €279.

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

The Company’s management, with the participation of our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of the Company’s disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of December 31, 2025. The Company’s disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports the Company files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to the Company’s management, including the Company’s Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, the Company’s management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints that require the Company’s management to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's management evaluated the effectiveness of its internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that evaluation, the Company’s management has concluded that, as of December 31, 2025, our internal controls over financial reporting were effective.

Changes in Internal Control over Financial Reporting

There were no changes to the Company’s internal control over financial reporting during the fourth quarter of 2025 that materially affected, or are reasonably likely to materially affect, the Company’s 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

Insider Adoption or Termination of Trading Arrangements

During the year ended December 31, 2025, two members of our Board of Directors adopted trading arrangements intended to satisfy the Rule 10b5-1 affirmative defense. Rostislav Raykov adopted a trading arrangement on September 19, 2025, covering the disposition of up to 109,184 shares of the Company's common shares, which is scheduled to terminate on June 9, 2026. Chris Rallis adopted a trading arrangement on May 19, 2025, covering the disposition of up to 18,406 shares of the Company's common shares, which will terminate on June 9, 2026, unless earlier terminated in accordance with its terms.

No additional directors or officers informed us of the adoption, modification or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The Company has an insider trading policy that governs the purchase, sale, and other dispositions of its securities by directors, officers, employees, and contractors, as well as by the Company itself. We believe that the insider trading policy is reasonably designed to promote compliance with insider trading laws, rules, and regulations and applicable listing standards. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.

The remaining information required by this Item is incorporated herein by reference from our Proxy Statement for our 2026 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2026 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2026 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2026 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2026 Annual Meeting of Stockholders.

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
4.1	Fennec Pharmaceuticals, Inc. Description of the Registrant's Securities	Exhibit 4.1 to the Form 10-K of the Company filed March 29, 2024
10.1	Fennec Pharmaceuticals, Inc. 2020 Equity Incentive Plan*	Schedule B to the Management Proxy Circular of the Company filed April 25, 2025
10.2	Executive Employment Agreement dated May 3, 2010 by and between Fennec Pharmaceuticals Inc. 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 Pharmaceuticals Inc. and Robert Andrade*	Exhibit 10.40 to the Form 10-Q of the Company filed November 12, 2015
10.5	Form of Stock Option Award Agreement under 2020 Equity Incentive Plan*	Exhibit 10.5 to the Form 10-K of the Company filed March 26, 2025
10.6	Form of Restricted Stock Award Agreement under 2020 Equity Incentive Plan*	Exhibit 10.6 to the Form 10-K of the Company filed March 26, 2025
10.7	Confidential Separation Agreement between Fennec Pharmaceuticals (EU) Limited, Fennec Pharmaceuticals Inc., and Adrian Haigh, dated June 30, 2024*	Exhibit 10.1 to the Form 8-K of the Company filed July 2, 2024
10.8	Confidential Separation Agreement between Fennec Pharmaceuticals, Inc. and Rostislav Raykov, dated August 5, 2024*	Exhibit 10.1 to the Form 8-K of the Company filed August 7, 2024
10.9	Executive Employment Agreement between Fennec Pharmaceuticals, Inc. and Jeffrey S. Hackman, dated August 5, 2024*	Exhibit 10.2 to the Form 8-K of the Company filed August 7, 2024

Exhibit No.	Description	Location
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	Securities Purchase Agreement, dated as of August 1, 2022, by and between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 10.1 to the form 8-K of the Company filed August 1, 2022
10.12	First Closing Senior Secured Convertible Note, dated August 19, 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 Senior Secured Convertible Note, 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
10.14	First Amendment to Securities Purchase Agreement, dated as of December 4, 2023, between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 10.1 to the Form 8-K of the Company filed December 6, 2023
10.15	Third Closing Senior Secured Convertible Note, dated as of December 4, 2023, between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 4.1 to the Form 8-K of the Company filed December 6, 2023
10.16	License and Supply Agreement, dated March 15, 2024, between Fennec Pharmaceuticals, Inc. and Norgine Pharma UK Limited	Exhibit 10.1 to the Form 8-K of the Company filed March 21, 2024
10.17	Waiver and Redemption Agreement, dated December 18, 2024, between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LP	Exhibit 10.1 to the Form 8-K of the Company filed December 20, 2024
19	Fennec Pharmaceuticals, Inc. Insider Trading Policy, dated July 11, 2009.	Exhibit 10.16 to the Form 10-K of the Company filed March 29, 2024
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
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
97	Fennec Pharmaceuticals, Inc. Incentive Compensation Recovery Policy	Exhibit 97 to the Form 10-K of the Company filed March 29, 2024
99.1	Press Release for Fiscal Year Ended December 31, 2025	Filed herewith

Exhibit No.	Description	Location
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/ Jeffrey Hackman
Jeffrey Hackman
Chief Executive Officer

Date: March 27, 2026

We, the undersigned directors and officers of Fennec Pharmaceuticals Inc., do hereby constitute and appoint Jeffrey Hackman, 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/ Jeffrey Hackman **Jeffrey Hackman**	Chief Executive Officer (principal executive officer) and Director	March 27, 2026
/s/ Robert Andrade **Robert Andrade**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 27, 2026
/s/ Dr. Khalid Islam **Dr. Khalid Islam**	Director	March 27, 2026
/s/ Chris A. Rallis **Chris A. Rallis**	Director	March 27, 2026
/s/ Marco Brughera **Marco Brughera**	Director	March 27, 2026
/s/ Rostislav Raykov **Rostislav Raykov**	Director	March 27, 2026
/s/ Jodi Cook **Jodi Cook**	Director	March 27, 2026

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. (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, shareholders' equity (deficit), 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, 2025 and 2024, 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. 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, audits 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 were 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 judgment.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (Continued)

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 separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Global Distributors - Estimated Product Allowances and Discounts

Critical Audit Matter Description

As described in Note 2 to the consolidated financial statements, the Company recognizes revenues based on the net sales price, which includes estimates of variable consideration for which reserves are established primarily from rebates, chargebacks, discounts, returns, and other allowances. Further, certain distributors provide distinct and estimable services to the Company in exchange for product allowances. The estimated fair value of distinct and estimable services performed by the distributor and the attribution of those amounts to the period of benefit are important factors in the determination of net sales price and requires subjective management assumptions. Allowances provided to distributors in excess of the estimated fair value of services received by the Company are presented as sales discounts. Allowances provided to such distributors during the year ended December 31, 2025 for distinct and estimable distributor services totaled $5.4 million, of which $1.7 million is presented as prepaid expenses as of December 31, 2025.

How the Critical Audit Matter was Addressed in the Audit

Auditing estimates of the amount and timing of distinct distributor services provided to the Company was challenging and judgmental because the estimates involve significant measurement uncertainty about the fair value of services received by the Company and the periods that such services were rendered to the Company. A high degree of auditor judgment, subjectivity and effort was required in performing procedures and evaluating evidence related to management's assumptions in these areas. Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others:

- We obtained and read related customer contracts to obtain an understanding of the contractual responsibilities of the parties; we evaluated management's accounting policies and practices with respect to distinct distributor provided services for compliance with accounting principles generally accepted in the United States of America; and we obtained an understanding of management's monitoring and oversight of such services.

- Through interviews, inquiries, observations, and examination of Company-prepared analyses, we obtained an understanding of the significant management assumptions behind the potentially significant components of the distributor allowances, including the nature of each allowance and the amounts estimated by management. Through interviews, inquiries, and observations, we obtained an understanding of the significant management assumptions supporting the fair value estimates of distinct distributor services and the timing of performance of services.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (Continued)

- We assessed the methodologies used to determine the allowances and the fair value of distinct distributor services and tested estimated percentages by corroborating the underlying data used to develop the estimate, which included evaluating the completeness and accuracy of such data. Our testing of allowances included comparing key assumptions to customer contracts, payment data, and other third-party sources, as applicable. Our testing of the fair value of distinct distributor services included evaluating management's estimate of costs to perform necessary services and assessing the reasonableness of estimated timeframes associated with the performance of those services.

- We evaluated information subsequent to the balance sheet date to determine whether there was any new information that would require adjustment to the previously estimated amounts.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

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

Irvine, California
March 27, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 36,788	$ 26,634
Accounts receivable, net	23,221	12,884
Prepaid expenses	3,738	3,080
Inventory	1,565	1,060
Other current assets	1,731	466
Total current assets	67,043	44,124
Non-current assets		
Non-current accounts receivable, net	2,791	—
Other non-current assets, net of amortization	717	822
Total non-current assets	3,508	822
Total assets	$ 70,551	$ 44,946
Liabilities and shareholders' equity/(deficit)		
Current liabilities:		
Accounts payable	$ 4,635	$ 3,241
Accrued liabilities	5,635	3,428
Operating lease liability - current	—	2
Contract liability - current	248	248
Total current liabilities	10,518	6,919
Non-current liabilities		
Term loan	—	18,206
PIK interest	—	1,271
Debt discount	—	(139)
Contract liability - long-term	24,561	24,561
Total non-current liabilities	24,561	43,899
Total liabilities	35,079	50,818
Commitments and contingencies (Note 7)		
Shareholders' equity/(deficit)		
Common stock, no par value; unlimited shares authorized; 34,163 shares issued and outstanding (2024 - 27,527)	189,906	145,608
Additional paid-in capital	73,745	66,958
Accumulated deficit	(229,422)	(219,681)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' equity/(deficit)	35,472	(5,872)
Total liabilities and shareholders' equity/(deficit)	$ 70,551	$ 44,946

(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, 2025	December 31, 2024
Revenue		
Product sales, net	$ 44,642	$ 29,580
Licensing revenue	—	17,958
Total net revenues	44,642	47,538
Operating expenses:		
Cost of product sales	3,764	3,184
Research and development	250	307
Selling and marketing	18,616	18,426
General and administrative	28,294	23,053
Total operating expenses	50,924	44,970
(Loss)/income from operations	(6,282)	2,568
Other income/(expense)		
Unrealized foreign exchange gain/(loss)	28	(82)
Amortization expense	(64)	(89)
Unrealized loss on securities	(2)	(81)
Loss on debt extinguishment (Note 8)	(2,022)	—
Interest income	787	1,682
Interest expense	(2,080)	(4,069)
Total other expense	(3,353)	(2,639)
Loss before income tax	(9,635)	(71)
Income tax	(106)	(365)
Net loss	$ (9,741)	$ (436)
Basic net loss per common share	$ (0.34)	$ (0.02)
Diluted net loss per common share	$ (0.34)	$ (0.02)
Weighted-average number of common shares outstanding basic	28,577	27,294
Weighted-average number of common shares outstanding diluted	28,577	27,294

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
	Number (Note 6)	Amount				
Balance at December 31, 2023	**27,027**	**$ 144,307**	**$ 62,073**	**$ (219,245)**	**$ 1,243**	**$ (11,622)**
Equity-based compensation - employees	—	—	5,061	—	—	5,061
Exercise of stock options	342	1,301	—	—	—	1,301
Restricted stock release	158	—	(176)	—	—	(176)
Net loss	—	—	—	(436)	—	(436)
Balance at December 31, 2024	**27,527**	**145,608**	**66,958**	**(219,681)**	**1,243**	**(5,872)**
Equity-based compensation - employees	—	—	7,033	—	—	7,033
Issuance of common stock, net of offering costs	6,037	42,049	—	—	—	42,049
Warrant exercise	9	59	(59)	—	—	—
Exercise of stock options	400	2,190	—	—	—	2,190
Restricted stock release	190	—	(187)	—	—	(187)
Net loss	—	—	—	(9,741)	—	(9,741)
Balance at December 31, 2025	**34,163**	**$ 189,906**	**$ 73,745**	**$ (229,422)**	**$ 1,243**	**$ 35,472**

(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, 2025	December 31, 2024
Cash flows provided by (used in)/provided by:		
Operating activities:		
Net loss	$ (9,741)	$ (436)
Adjustments to reconcile net loss to net cash (used in)/provided by operating activities:		
Inventory reserve	773	517
Allowance for credit losses	2,103	3,803
Amortization of contract asset	103	800
Amortization of debt access fees	—	21
Amortization of debt discount	65	138
Unrealized loss on securities	2	81
Equity-based compensation	7,033	5,061
Loss on debt extinguishment	2,022	—
PIK interest	—	52
Changes in operating assets and liabilities:		
Accounts receivable	(12,440)	(7,873)
Prepaid expenses	(658)	(505)
Inventory	(1,278)	579
Other assets	(1,267)	796
Other non-current assets	(2,791)	—
Accounts payable	1,394	(537)
Accrued liabilities	2,207	(326)
Contract liability	—	24,809
Net cash (used in)/provided by operating activities	(12,473)	26,980
Financing activities:		
Issuance of shares, options exercise	2,190	1,301
Proceeds form the issuance of common stock, net of offering costs	42,049	—
Payment of long-term debt	(19,477)	(13,000)
Prepayment penalty on debt repayment	(1,948)	—
Cash paid for taxes on restricted share release	(187)	(176)
Deferred issuance costs	—	(1,740)
Net cash provided by/(used in) by financing activities	22,627	(13,615)
Increase in cash and cash equivalents	10,154	13,365
Cash and cash equivalents - Beginning of year	26,634	13,269
Cash and cash equivalents - End of year	$ 36,788	$ 26,634
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 4,160	$ 3,821
Cash paid for taxes	$ 748	$ —
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 2
Financed insurance policy	$ 393	$ 386

(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., a corporation existing under the laws of British Columbia ("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. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian corporation, and Fennec Pharmaceuticals (EU) Limited, an Ireland company ("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., and Fennec Limited, 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, 2025, the Company incurred a net loss from operations of $6,282. At December 31, 2025, it had an accumulated deficit of $229,422 and had experienced negative cash flows from operating activities in the amount of $12,473 for the year ended December 31, 2025.

Senior Secured Convertible Notes

In August 2022, the Company entered into a Securities Purchase Agreement with Petrichor Opportunities Fund I LP providing for the issuance of up to $45,000 of senior secured floating-rate convertible notes due August 2027. Between August 2022 and December 2023, the Company issued an aggregate of $30,000 of Notes under this agreement.

In December 2024, the Company redeemed approximately $13,000 of Notes, including payment-in-kind interest.

On November 17, 2025, the Company redeemed all remaining outstanding Notes for an aggregate redemption price of approximately $21,700, including principal, accrued interest, and applicable redemption fees. The redemption was funded primarily using proceeds from the Company's November 2025 public equity offering (Note 6).

As of December 31, 2025, no convertible notes were outstanding.

License Agreement

In March 2024, the Company announced that is had secured an exclusive licensing agreement with Norgine Pharma UK Limited ("Norgine"), to commercialize PEDMARQSI in Europe, Australia and New Zealand. The deal provided the Company with approximately $43 million upfront, with the potential of another approximately $230 million in future royalties and milestone payments.

The Company believes current funds, which include funds from the upfront payment from Norgine, 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.

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

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Fennec and 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, amount and timing of marketing and other services performed by certain distributors, allowance against trade receivables, and measurement of stock-based compensation. Actual results could differ from those estimates.

Credit Losses

The Company estimates and records a provision for its expected credit losses related to its trade receivables. The Company considers historical collection rates, the current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer, as the Company determined that risk profile of its customers may vary based on certain characteristics such as credit history, past payment history and geography. Each class of customer component is analyzed for estimated credit losses individually. In doing so, the Company establishes a customer profile, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the life sciences industry to estimate if there are current expected credit losses within its trade receivables based on the trends and the Company's expectation of the future status of such economic and industry-specific factors. Also, specific allowance amounts are established based on review of outstanding invoices to record the appropriate provision for customers that have a higher probability of default.

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 and employees are supporting only one operating segment which is the production and commercialization of PEDMARK.

Stock-Based Compensation

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

The Company uses the Black-Scholes option pricing model to value stock option awards without market conditions, which requires the Company to make certain assumptions regarding the expected volatility of its common stock price, the expected term of the option grants, the risk-free interest rate and the dividend yield with respect to its common stock. The Company calculates volatility using its historical stock price data. Due to the lack of the Company's own historical data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the Company's stock option grants. Under this approach, the weighted-average expected life is presumed

to be the average of the vesting term and the contractual term of the option. The risk-free interest rate used for each grant is based on the United States Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and at present, has no intention to pay cash dividends.

In May and August 2025, the Board of Directors approved grants of performance-based units (PSUs) whereby vesting depends on the achievement of specified revenue performance milestones through December 31, 2025. The Company estimates the likelihood of achievement of the performance milestones for all PSU awards at the end of each reporting period, and to the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. As of December 31, 2025, the Company determined that the applicable revenue performance milestones had been achieved and recognized the related PSU compensation cost in full.

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.

Revenue Recognition

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

License Agreements

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

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

Contingent milestones at contract inception are estimated at the amount which is not probable of a material reversal and included in the transaction price using the most likely amount method. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance

obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development or sales-based milestone payments that may not be subject to a material reversal and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

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

Costs to Obtain Contract

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

Net Product Revenue

On September 20, 2022, the FDA approved PEDMARK® in the United States to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. PEDMARK® became commercially available on October 17, 2022. PEDMARK® is the Company’s first commercial product. Amongst the Company’s customers are distributors which subsequently resell the Company’s products to health care providers and patients. In addition to distribution agreements, 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 U.S. based 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.

The Company also utilizes select distributors to introduce its product into global markets. These distributors take on the function of shipping, storage, marketing and other services related to the sale of our product. We record distribution and other fees paid to these distributors as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services received. If both conditions are met, we record the consideration paid to the distributor as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

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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 for prompt payment which may range from 0.5% to 2.0%. The Company expects its customers will earn 100% of their prompt payment discounts and, therefore, the Company deducts the full amount of these discounts from total product sales when revenues are recognized.

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

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

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

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

The following table summarizes net product revenues for PEDMARK® in the years ended December 31, 2025, and 2024, respectively:

	Year Ended	
	December 31, 2025	December 31, 2024
Product revenues:		
Gross product revenues	$ 53,807	$ 38,910
Discounts and allowances	(9,165)	(9,330)
Net product revenues	$ 44,642	$ 29,580

For the years ended December 31, 2025 and 2024, the Company had three distributors that represented more than 10% of net sales.

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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, 2025, and 2024 were as follows:

In thousands	Chargebacks, Discounts for Prompt Pay and Other Allowances	Rebates, Customer Fees/Credits and Co-Pay Assistance	Totals
Balance at December 31, 2023	$ 365	$ 430	$ 795
Provision related to sales made in:			
Current period	1,909	6,573	8,482
Prior periods	—	—	—
Payments and customer credits issued	(1,998)	(6,296)	(8,294)
Balance at December 31, 2024	276	707	983
Provision related to sales made in:			
Current period	2,422	1,340	3,762
Prior periods	—	—	—
Payments and customer credits issued	(2,221)	(624)	(2,845)
Balance at December 31, 2025	$ 477	$ 1,423	$ 1,900

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, both specialty and other select global distributors. Amounts estimated for the associated chargebacks, cash discounts for prompt payment and any allowances for credit losses are booked as a reserve against accounts receivable and reduction of revenue. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company considers various factors, including loss history, individual credit risk associated with each customer, and the current and future condition of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such a customer. For customers that are large specialty distributors, the Company considered the risk of potential credit losses to be low. Sales to other select global distributors have increased the potential for losses. The Company evaluates the risk of credit losses on sales on an individual basis using the above-mentioned criteria. The Company had an allowance for credit losses of $5,904 as of December 31, 2025.

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. Cost of products sold also consists of shipping and other third-party logistics and distribution costs for the Company’s product. As of December 31, 2025, the Company capitalized approximately $1,565 of costs as inventory, net of obsolescence reserve, on the consolidated balance sheet. Of the items capitalized, $1,274 was capitalized as raw materials, $153 as WIP and $138 was capitalized into finished goods. There was a reserve against WIP valuation for inventory which the Company believes will expire before it is sold in the amount of $1,290.

Cash and Cash Equivalents

Cash equivalents consist of highly liquid investments with original maturities at the date of purchase of three months or less.

The Company places its cash and cash equivalents in investments held by highly rated financial institutions in accordance with its investment policy designed to protect the principal investment. As of December 31, 2025, the Company had $36,788 in cash and money market accounts (2024 - $26,634). Money market investments typically have minimal risks. While the Company has not experienced any loss or write-down of its money market investments, the amounts it holds in money market accounts are substantially above the $250 amount insured by the FDIC and may lose value.

Financial Instruments

Financial instruments recognized on the consolidated balance sheets at December 31, 2025 and 2024, 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

At December 31, 2025, the Company had 111 warrants with a weighted average strike price of $8.11 outstanding to purchase common shares that have a weighted average life of 1.68 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.

The Company conducts certain research and development activities under clinical trial and other research agreements with third parties and records expenses for these activities based on estimates of the work performed during the reporting period. In developing these estimates, the Company considers factors such as the terms of the underlying contracts, progress of patient visits and related clinical procedures, the achievement of contractual milestones, and data received from CROs and other service providers, and adjusts accruals as actual information becomes available.

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

Concentrations of Credit Risk

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

The Company's trade receivables includes amounts billed to customers for product sales of PEDMARK®. In the U.S., the customers are a limited group of specialty distributors, and direct customers, and accordingly, the Company considers the risk of potential credit losses to be low. The Company also sells to a select group of global distributors. These global distributors are established companies and although the Company regards credit losses with these distributors to be low, it does recognize the increased potential for credit losses with this group.

Income Taxes

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of December 31, 2025, and 2024, we maintained a full valuation allowance against our deferred tax assets.

The provisions of the Financial Accounting Standards Board ("FASB") ASC 740-10, Uncertainty in Income Taxes, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, 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 Transaction

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

Loss Per Share

Basic net loss per share was computed by dividing net loss by the weighted-average number of common shares outstanding during the year. Diluted net loss per share was computed using the same method, except the weighted-average number of common shares outstanding included convertible debentures, performance share units, restricted share units, stock options and warrants, if dilutive, as determined using the if-converted and treasury stock methods. Accordingly, at December 31, 2025, warrants to purchase 0.1 million of our common shares, performance share units covering 0.3 million of our common shares, restricted share units to obtain 0.4 million of our common shares, and options to purchase 5.9 million of our common shares were excluded from the computation of diluted net loss per share because their inclusion would have been antidilutive. At December 31, 2024, warrants to purchase 0.2 million of our common shares, restricted share units to obtain 0.3 million of our common shares and options to purchase 5.9 million of our common shares were excluded from the computation of diluted net loss per share because their inclusion would have been antidilutive; there were no performance share units outstanding at that date.

Recent Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. This guidance will be effective for annual periods beginning the year ended December 31, 2025. The Company adopted ASU 2023-09 on January 1, 2025, on a prospective basis, and the adoption affected only the Company's income tax disclosures and did not have an impact on its consolidated results of operations, financial position or cash flows.

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure of additional disaggregated information about significant expenses within relevant income statement captions, such as purchases of inventory, employee compensation, depreciation, amortization and depletion. The new guidance is effective for annual periods beginning after December 15, 2026, and interim periods within annual periods beginning after December 15, 2027. We are currently evaluating the impact of this standard on our consolidated financial statements.

In July 2025, the FASB issued ASU No. 2025-05, "Measurement of Credit Losses for Accounts Receivable and Contract Assets ("ASU 2025-05"). The guidance in ASU 2025-05 amends ASC Topic 326, Financial Instruments-Credit Losses, to provide a practical expedient to simplify estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC Topic 606, Revenue from Contracts with Customers. The practical expedient, if elected, allows entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. The standard is effective for annual fiscal years beginning after December 15, 2025 and interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. Entities that elect the practical expedient should apply the guidance prospectively. The Company is currently evaluating the impact that the adoption of ASU 2025-05 may have on its consolidated financial statements.

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,	
	2025	2024
Numerator:		
Net loss	$ (9,741)	$ (436)
Denominator:		
Weighted-average common shares, basic	28,577	27,294
Weighted-average common shares, diluted	28,577	27,294
Net loss per share, basic and diluted	**$ (0.34)**	**$ (0.02)**

The following outstanding options, restricted share units, 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,	
	2025	2024
Options to purchase common shares	5,853	5,855
Restricted share units to obtain common shares	387	324
Performance share units to purchase common shares	314	—
Warrants to purchase common shares	111	150

4. Stock Options

Equity Incentive Plan

The Company maintains the 2020 Equity Incentive Plan (the "2020 Plan" or the "Plan"), which is administered by the Compensation Committee of the Board of Directors. The 2020 Plan provides for the issuance of stock options, restricted share units ("RSUs"), and other equity-based awards to employees, directors, officers, and consultants of the Company. The Compensation Committee is responsible for determining eligible participants and approving individual award grants under the 2020 Plan.

On April 24, 2025, the Company's Board of Directors approved an amendment to the Plan to: (i) increase the number of common shares available for issuance under the Plan (excluding common shares issued prior to the date of the meeting pursuant to the exercise of options and vesting of RSUs) to 8,500 common shares, representing approximately 30.8% of

the total issued and outstanding common shares as of the date of the circular; and (ii) include provisions for an employee stock purchase program. The amendment was subsequently approved by the Company's shareholders on June 3, 2025.

Prior to this amendment, the maximum number of equity instruments issuable under the Plan, together with the Company's prior stock option plan, was limited to 25% of the Company's issued and outstanding common shares. Based on the then-current outstanding share count, this equated to a maximum of 6,825 common shares available for issuance.

All stock options granted under the Plan have an exercise price equal to the fair value of the Company's common shares on the date of grant. Options generally vest over a period of up to three years and are exercisable for a period of up to ten years from the grant date. Awards under the Plan may be denominated in either U.S. or Canadian dollars.

In November 2025, we filed a registration statement on Form S-8 registering 8,500 shares of common stock for issuance under the Fennec Pharmaceuticals Inc. 2020 Equity Incentive Plan. These shares are intended to support future equity-based compensation awards.

The Company recognizes stock-based compensation expense for all share-based awards granted to employees and non-employees based on the fair value of the awards on the grant date.

A summary of the stock option transactions, U.S. dollar grants, for the years ended December 31, 2025 and 2024 is below. Unrecognized stock-based compensation at December 31, 2025 was $4,223 that will be recognized over a weighted-average service period of 1.69 years. There are no outstanding $CAD denominated options.

Summary of Option Activity

	Number of Options (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2023	**4,798**	**$ 4.08-10.96**	**$ 6.27**
Granted	1,825	4.23-7.29	5.84
Exercised	(342)	2.36-5.81	3.25
Forfeited	(426)	7.12-8.00	7.60
Outstanding and exercisable at December 31, 2024	**5,855**	**2.36-8.00**	**6.22**
Granted	658	6.50-9.11	7.33
Exercised	(401)	5.00-5.65	5.40
Forfeited	(259)	4.23-7.18	6.53
Outstanding and exercisable at December 31, 2025	**5,853**	**$ 4.23-9.11**	**$ 6.38**

Summary of Option Remaining Life

Number Outstanding and Exercisable at December 31, 2025	Weighted Average Strike Price December 31, 2025	Weighted Average Remaining Life
(in thousands)	US Dollars	(years)
5,853	$6.38	6.19

Stock compensation expense for the years ended December 31, 2025, and 2024 was $7,033 and $5,061, 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 during the years ended December 31, 2025, and 2024 was $7.33 and $4.55, respectively. The intrinsic value (being the difference between the share price at December 31, 2025 and exercise price) of stock options exercisable at December 31, 2025 was $6,988. The intrinsic value of options exercised during the year ended December 31, 2025, was $2,214.

The fair value of all options vested during the year ended December 31, 2025, was $3,041. The fair values of options granted in years ended December 31, 2025 and 2024 were estimated on the date the options were granted based on the

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

Black-Scholes option-pricing model, using the following weighted average assumptions for all options with a ten-year expiration:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
Expected dividend	-	%	-	%
Risk-free interest rate	3.83 - 4.19	%	3.64 - 5.15	%
Expected volatility	71.04 - 161.67	%	55.00 - 162.00	%
Expected life	1.50 - 6.0 years		1.50 - 6.0 years	

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

Performance-Based Units

In May and August 2025, the Board of Directors approved PSU grants whereby vesting depends on certain revenue performance milestones during the year ended December 31, 2025. The Company estimates the likelihood of achievement of performance milestones for all PSU awards at the end of each reporting period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. The performance milestones were achieved for the year ended December 31, 2025. The expense of $2,387 was recognized for 2025.

During 2025, the Company granted a total of 320 performance units and 6 units were forfeited, resulting in 314 unvested performance units outstanding at December 31, 2025 with a weighted-average grant-date fair value of $7.46 per share.

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, 2025, and 2024. Prior to June 2021, there was no activity involving RSUs. During the year ended December 31, 2025, 283 RSUs were awarded, 7 were forfeited and 213 were released from restriction. The Company recognized $1,697 in RSU expense for the year ended December 31, 2025, and $1,382 for the same period in 2024. Standard vesting of RSUs is over three years with 1/3 vesting on the first anniversary date of the grant and then 1/24 on the last day of each subsequent month. The Compensation Committee may also award RSUs with alternative vesting.

Summary of RSU Activity	Number of Restricted Share Units (thousands)
Outstanding at December 31, 2023	**218**
Awarded	316
Forfeited	(180)
Released	(30)
Outstanding at December 31, 2024	**324**
Awarded	283
Forfeited	(7)
Released	(213)
Outstanding at December 31, 2025	**387**

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 the Processa Pharmaceuticals Inc. ("Processa") common shares held by the Company by taking into consideration valuations obtained from public financial markets. The Company uses Yahoo Finance to obtain share price data and Oanda for foreign currency pricing services to estimate fair value. These inputs include reported trades of and broker- dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

As of December 31, 2025, the Company had financial assets valued based on Level 1 inputs consisting of cash and cash equivalents and Processa common shares. The Company also had financial assets based on Level 2 inputs consisting of money market funds. During the year ended December 31, 2025, the Company did not have any transfers of financial assets between Levels 1 and 2.

Assets/Liabilities Measured at Fair Value on a Recurring Basis

	Fair Value Measurement at December 31, 2025 and December 31, 2024 (in thousands)							
	Quoted Price in Active Market for Identical Instruments Level 1		Significant Other Observable Inputs Level 2		Significant Unobservable Inputs Level 3		Total	
	2025	2024	2025	2024	2025	2024	2025	2024
Assets								
Cash and cash equivalents	$ 3,072 (1)	$2,020 (1)	$33,716	$24,614	—	—	$36,788	$26,634
Processa common shares	2 (2)	2	—	—	—	—	2	2

(1) The Company held approximately, $3,072 in cash as of December 31, 2025, of which approximately $154 was in Canadian funds and $327 in Euro (both translated into U.S. dollars). As of December 31, 2024, the Company held approximately $2,020 in cash, of which approximately $110 was in Canadian funds and $245 in Euro (both translated into U.S. dollars).

(2) The Company has 51 unrestricted common shares of Processa (Nasdaq: PCSA).

6. Stockholders' Equity

Authorized Capital Stock

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

Public Offering and Concurrent Private Placement

On November 17, 2025, the Company completed an underwritten public offering of 5,367 common shares, including 700 common shares issued upon the underwriters' full exercise of their option to purchase additional shares, at a public offering price of $7.50 per share, for gross proceeds of approximately $40.25 million before deducting underwriting discounts and offering expenses. Concurrently, the Company completed a non-brokered private placement of common shares in Canada to certain existing institutional shareholders at a price of $7.50 per share, for aggregate gross proceeds of approximately $5.025 million before offering expenses. The Company used a substantial portion of the combined net proceeds from these

equity offerings to redeem all remaining outstanding senior secured convertible notes, with the balance intended for working capital and other general corporate purposes.

Warrants to Purchase Common Shares

At December 31, 2025, the Company had warrants outstanding to purchase 111 common shares at a weighted average exercise price of $8.11.

The following table summarizes our warrant activity for the years ended December 31, 2025 and 2024.

	Number of Warrants (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2023	**$ 150**	**$ 7.71**	**$ 7.71**
Granted	—	—	—
Outstanding and exercisable at December 31, 2024	**$ 150**	**$ 7.71**	**$ 7.71**
Exercised	(39)	**6.80**	6.80
Outstanding and exercisable at December 31, 2025	**$ 111**	**$ 6.80-8.11**	$ **8.11**

7. Commitments and Contingencies

Litigation

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

Under the Food, Drug, and 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, which is September 20, 2029.

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

On April 23, 2024, we were granted US 11,964,018 Patent (the "US '018 Patent) covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around May 8, 2024, and has an expiration date of July 2039. On May 28, 2024, we were granted US 11,992,530 Patent (the "US '530 Patent") covering a method of using our PEDMARK® product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 20, 2024, and has an expiration date of July 2039. On June 4, 2024, we were granted US 11,998,604 Patent (the "US '604 Patent") covering a method of using our PEDMARK product to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer, which was listed in the Orange Book on or around June 24, 2024, and has an expiration date of July 2039.

On June 13, 2024, we filed a Motion for Leave to File a Third Amended Complaint to focus the ANDA litigation against CIPLA on the US '018 Patent and the US '793 Patent only. The non-asserted patents remain listed in the Orange Book. On July 22, 2024, CIPLA filed a response indicating that they do not oppose our Motion for Leave to File a Third Amended Complaint. On July 30, 2024, the court granted us leave to file the Third Amended Complaint, which we filed on September 16, 2024.

In coordination with the Third Amended Complaint, we entered into a covenant not to sue CIPLA on the US '363 Patent, US '728 Patent, US '984 Patent, US '530 Patent, and US '604 Patent, subject to the limitation that such shall not apply to the extent CIPLA alters the product or formulation described in its FDA ANDA application.

On May 27, 2025, we were granted US 12,311,026 (the "US '026 Patent") covering a method of using pharmaceutical compositions comprising sodium thiosulfate and specific stabilizers to reduce ototoxicity in a patient receiving a platinum based chemotherapeutic for the treatment of a cancer. The US '026 Patent has an expiration date of July 2039.

On May 27, 2025, we filed suit against the CIPLA entities in the United States District Court for the District of New Jersey (Case No. 2:25-cv-05709), for infringement of the US '026 Patent based on the Cipla entities' ANDA filing. Subsequently, we filed a Motion to Consolidate Case No. 2:25-cv-05709 and Case No. 2:23-cv-00123.

On July 14, 2025, the court granted the Motion to Consolidate Case No. 2:25-cv-05709 with Case No. 2:23-cv-00123.
On July 14, 2025, the court issued its Order on Claim Construction on two claim terms in dispute in the '793 Patent and '018 Patent, adopting our proposed constructions for both.

On August 25, 2025, the CIPLA entities filed an Answer and Counterclaims to the complaint, alleging that the '026 Patent was invalid, not infringed, and/or unenforceable.

On September 18, 2025, we filed an Answer to CIPLA's Counterclaims.

On March 16, 2026, Fennec entered into an agreement with Cipla Limited and Cipla USA, Inc. to settle the litigation between them regarding Cipla's application to FDA for approval to market a generic version of Fennec's PEDMARK® (sodium thiosulfate injection) product. *See Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc*., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the agreement, the lawsuit will be dismissed with each party bearing their own costs, and Cipla will not enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain circumstances.

Executive Severance

In the event of termination of Mr. Hackman's (Chief Executive Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one-time severance payment equal to twelve months of salary (currently $586). In the event of termination of Mr. Andrade's (Chief Financial Officer) employment with the Company other than for cause, the Company will be obligated to pay him a one-time severance payment equal to nine months of salary which is equivalent to $362. Further, certain other Executive Employment Agreements generally provide that if employment is terminated without "Cause" (as defined in the applicable Executive Employment Agreement) and other conditions are satisfied, then such executive officer shall receive as severance an amount equal to their then current base salary for a period of nine (9) months, less standard withholdings for tax and social security purposes.

Leases

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

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

On August 1, 2023, the Company entered into a second Office Service Agreement (the "Second Office Service Agreement") with Regus to lease office space in Dublin, Ireland. Per the terms of the Second Office Service Agreement, the monthly rent payments are $2. The Company was required to pay a security deposit of $5, which is the equivalent of two months rent. The Second Office Service Agreement commenced on August 1, 2023 and terminated on January 31, 2025.

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, 2025, the Company does not offer matching contributions.

8. Term Loans

In August 2022, the Company entered into a Securities Purchase Agreement with Petrichor Opportunities Fund I LP providing for the issuance of up to $45,000 of senior secured floating-rate convertible notes due August 2027. Between August 2022 and December 2023, the Company issued an aggregate of $30,000 of Notes under this agreement.

In December 2024, the Company redeemed approximately $13,000 of Notes, including payment-in-kind interest.

On November 17, 2025, the Company redeemed all remaining outstanding Notes for an aggregate redemption price of approximately $21,729, including principal, accrued interest, and applicable redemption fees. The redemption was funded primarily using proceeds from the Company's November 2025 public equity offering (Note 6).

As of December 31, 2025, no convertible notes were outstanding.

Fennec Pharmaceuticals Inc.
Notes to the Consolidated Financial Statements
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9. Income Taxes

We account for income taxes in accordance with ASC 740, Income Taxes. Our income tax expense (benefit) is based on income (loss) from continuing operations before income taxes and reflects current and deferred tax expense (benefit) attributable to U.S. federal, state, and foreign jurisdictions. We adopted ASU 2023-09, Improvements to Income Tax Disclosures, on January 1, 2025 on a prospective basis. The adoption did not have an impact on our consolidated financial position or results of operations but resulted in expanded income tax disclosures. The Company operates in U.S., Canadian and Ireland 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, 2025	Year Ended December 31, 2024
Income (loss) from continuing operations before income taxes:		
Domestic loss	$ (14,327)	$ (12,127)
Foreign income	4,692	12,056
Total Pretax Income (Loss) From Continuing Operations	$ (9,635)	$ (71)
The provision for income taxes consists of the following (in thousands):		
Current income tax expense		
Federal	—	—
Provincial, local and other	—	—
Foreign	106	365
Deferred income tax expense		
Federal	—	—
Provincial, local and other	—	—
Foreign	—	—
Provision for income taxes	$ 106	$ 365

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
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A reconciliation of the combined Canadian federal and provincial income tax rate to our effective tax rate for the year ended December 31, 2025 is as follows:

	Year Ended December 31, 2025		
	Amount	Percent	
Loss before income taxes	$ (9,635)		
Federal Statutory Tax Rate and Tax Expense (1)	(1,515)	15.00	%
Provincial Tax (2)	(17)	0.18	
Foreign Tax Effects			
US			
Foreign Rate Differential	275	(2.91)	
US State Tax	61	(0.65)	
Non-deductible meals and entertainment	77	(0.82)	
Valuation allowance	(987)	10.43	
Effect of Cross-Border Tax Laws			
Domestic taxes on foreign earnings	118	(1.25)	
Tax Credits	39	(0.41)	
Non-taxable or Non-deductible Items			
Stock Compensation	1,055	(11.14)	
Valuation allowance	1,008	(9.64)	
Other	(8)	(0.08)	
Provision for income taxes	$ 106	1.12	%

(1) Represents the Canadian federal statutory income tax rate.
(2) Provincial taxes in Ontario comprised the majority of the tax effect in this category.

A reconciliation of the Canadian federal statutory income tax rates to our effective tax rate for the years ended December 31, 2024 is as follows:

	Year Ended December 31, 2024	
Domestic loss	$	(12,127)
Foreign income		12,056
Loss before income taxes	$	(71)
Income (loss) before income taxes		
Statutory tax rate		26.50 %
Expected provision for (recovery of) income tax		(19)
Permanent differences		1,629
Change in valuation allowance		20,059
Effect of tax rate changes and other		(22,034)
Provision for income taxes	$	(365)

(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, 2025 and December 31, 2024:

	December 31, 2025	December 31, 2024
Future tax assets:		
SR&ED expenditures	$ 2,086	$ 2,086
Income tax loss carryforwards	14,896	13,219
Non-refundable investment tax credits	158	197
Share issue costs	22	38
Fixed and intangible assets	24,244	30,750
Debt discount	64	27
Other	5,064	6,067
Gross future tax assets	46,534	52,384
Less: valuation allowance	(46,508)	(52,358)
Net future tax assets	$ 26	$ 26
Future tax liabilities:		
Investments	(26)	(26)
Gross future tax liabilities	$ (26)	$ (26)
Total deferred tax assets, net	-	-

For 2025, cash paid for income taxes, net of refunds received, was $418, all of which related to foreign income taxes in the United States; we did not pay any federal, provincial, or other foreign income taxes during the year.

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, but the Norgine deal will cause the Company to be closer to using its historical tax losses. Once those losses are used up, the Company will owe income taxes. As of December 31, 2025, the Company

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

has unclaimed Scientific Research and Experimental Development ("SR&ED") expenditures, income 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):		
2026	65,204	789,105
2027	20,150	651,278
2028	16,977	655,415
2029	650	616,910
2030	358	941,126
2031	—	1,013,499
2032	730	1,637,844
2033	365	2,159,126
2034	160	3,737,889
2035	805	9,215,474
2036	578	8,214,367
2037	—	1,298,877
2038	—	208,948
2039	—	—
2040	—	334,363
2041	2,894,601	—
2042	6,191,851	—
2043	6,455,938	—
2044	—	—
2045	499,093	
No expiration	36,833,705	—
Investment tax credits (expiry date):		
2025	82	—
2026	86	—
2027	47	—

10. License Agreement

License Agreement with Norgine Pharma UK Limited

On March 17, 2024, the Company announced that, through its wholly-owned subsidiary, Fennec Pharmaceuticals, Inc. entered into a License and Supply Agreement (the "Agreement") with Norgine Pharma UK Limited ("Norgine"), pursuant to which Norgine is granted an exclusive license to commercialize the Company's product PEDMARQSI® (known as PEDMARK in the United States) for all human indications in the European Economic Area, Switzerland, the United Kingdom, Australia and New Zealand (collectively, the "Territory"). On July 26, 2024, Norgine and Fennec amended the exclusive licensing agreement. The amended agreement maintains all principal payment terms with the primary addition of Norgine assuming responsibility for packaging and labeling of PEDMARQSI®.

Pursuant to the terms of the Agreement, Fennec shall receive the following payments from Norgine: (i) an upfront payment in the amount of €40,000 or approximately $43,200, which was paid to Fennec on March 15, 2024, (ii) up to €210,000 (or approximately $230,000) upon the achievement of certain regulatory and commercial milestones, and (iii) tiered royalty payments based on net sales of PEDMARQSI® in the Territory, which royalty payment range from mid-teen percent to mid-twenty percent based on the aggregate net sales of PEDMARQSI® in the Territory. The tiered royalty payments are subject to material reduction if an alternative or generic version of PEDMARQSI® becomes available in any respective country or jurisdiction within the Territory.

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

The Company evaluated the Agreement under ASC 606 and concluded that Norgine represents a customer in the transaction. There were two performance obligations: a license of functional IP and a material right for future supply. The Company will allocate the transaction price, including currently unrecognized variable consideration, to the two performance obligations based on estimated standalone selling price, which was estimated using projected cash flows. The initial transaction price consisted of the non-refundable upfront payment, a portion of which was allocated to and recognized as License Revenue in the first quarter of 2024 as the requirements for revenue recognition under ASC 606 were met. The portion of the transaction price associated with the material right is deferred and reflected as deferred revenue in the consolidated balance sheets. Deferred revenue associated with the material right is recognized as contract liabilities under the supply arrangement are made. The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are dependent on regulatory approvals and actions of third parties, and thus are highly susceptible to factors outside the Company's influence. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue or deferred as part of the material right in the period when the related sales threshold is met. All other milestones will be recognized as revenue or deferred as part of the material right immediately in the period the underlying milestone is achieved. Any consideration related to sales-based royalties will be recognized as revenue or deferred as part of the material right when the related sales occur. For year ended December 31, 2025, the Company recognized $426 of royalty revenue and did not recognize any milestone revenue payments from Norgine sales of PEDMARQSI® pursuant to the Agreement.

In conjunction with entering into the Agreement, the Company paid approximately $1,700 in incremental costs, which were capitalized and recorded within other non-current assets. The Company amortizes the asset over the period of expected benefit using a systematic basis that reflects the pattern of transfer to the customer. A portion that represents the license was recognized immediately and is recorded within selling and marketing expense in the consolidated statements of operations. As of December 31, 2025, $717 in incremental cost was capitalized.

11. Segment Reporting

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.

Fennec's chief operating decision maker is the senior executive team that includes the chief executive officer and chief financial officer. The chief operating decision maker uses net loss to evaluate income generated from segment assets (return on assets) in deciding whether to reinvest profits into the single segment or any other part of the entity, such as for acquisitions or to pay dividends.

The accounting policies of the operating segment are the same as those described in Note 2, Significant Accounting Policies. The chief operating decision maker evaluates the performance of the operating segment and allocates resources based on net loss that also is reported on the consolidated income statement as net loss. The measure of the operating segment assets is reported on the consolidated balance sheet as total assets.

The chief operating decision maker uses net loss to monitor budget versus actual results and to analyze cash flows in assessing performance of the segment and allocating resources. The significant expenses are presented in the Company's statements of operations.

Fennec Pharmaceuticals Inc.
Notes to the Consolidated Financial Statements
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12. Subsequent Events

On March 16, 2026, the Company entered into a settlement agreement with Cipla Limited and Cipla USA, Inc. (together, "Cipla") to resolve the litigation relating to Cipla's application to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of PEDMARK® (sodium thiosulfate injection), captioned Fennec Pharmaceuticals Inc. v. Cipla Limited and Cipla USA, Inc., C.A. No. 2:23-cv-00123-JKS-MAH (D.N.J.). Under the terms of the settlement, the lawsuit will be dismissed with each party bearing its own costs, and Cipla has agreed not to enter the market with its generic sodium thiosulfate product until September 1, 2033, or earlier under certain specified circumstances.

The settlement was entered into subsequent to December 31, 2025, and did not exist at that date. Accordingly, the settlement has been accounted for as a non-recognized subsequent event and no adjustments have been made to the consolidated financial statements as of and for the year ended December 31, 2025.

There were no other subsequent events that required adjustment to or disclosure in the accompanying financial statements.

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. 333-291616 and 333-294047) and the Registration Statement on Form S-3 (File No. 333-275452) of Fennec Pharmaceuticals Inc. (the "Company") of our report dated March 27, 2026, relating to the consolidated financial statements as of December 31, 2025 and 2024 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, 2025.

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/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
March 27, 2026

Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Jeffrey Hackman, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2025 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 27, 2026

By: /s/ Jeffrey Hackman
Jeffrey Hackman
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, 2025 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 27, 2026

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, 2025 (the "Report"), each of the undersigned, Jeffrey Hackman, 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 27, 2026

By: /s/ Jeffrey Hackman
Jeffrey Hackman
Chief Executive Officer

Date: March 27, 2026

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

FENNEC PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL YEAR 2025 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

~ Delivered Record Annual Revenue with Full-Year Net PEDMARK® Product Sales of $44.6 Million, Representing 50% Year-Over-Year Growth, and Q4 2025 Net Product Sales of $13.8 Million, Representing 75% Growth Over Q4 2024 Net Product Sales ~

~ Executed on 2025 Clinical Data Strategy to Expand Real-World Validation of PEDMARK® Across New Tumor Types and Patient Populations Through Independent, Institution-Led Research ~

~ Achieved Record Performance with All-Time High Patient Enrollments and Conversion Rates in Q4 2025, Reflecting Strong Field Execution ~

~ Completed Oversubscribed $42 Million Equity Offerings with Participation from New and Existing Investors ~

~ Announced Positive Topline Results from Investigator-Initiated Clinical Study of PEDMARK® in Japan to Reduce Cisplatin-Induced Hearing Loss ~

~ Management to Host Conference Call Today at 8:30 a.m. ET ~

Research Triangle Park, NC, March 24, 2026 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today reported its financial results for the fiscal year ended December 31, 2025 and provided a business update.

"Our 2025 results validate that our strategy is clear and the foundation we built over the past year is now propelling Fennec into its next chapter of growth. We delivered record net product sales, achieved significant growth within our Fennec HEARS® program, and advanced independent clinical evidence generation for PEDMARK® – all while driving quarter-over-quarter growth in every quarter in 2025. These results demonstrate increasing PEDMARK® adoption across key accounts and patient segments, effective field execution, and sustained progress across the organization," said Jeff Hackman, chief executive officer of Fennec Pharmaceuticals. "Concurrently, we strengthened our financial position through prudent operating decisions and strategic financial initiatives, including the closing of public and private offerings and the completion of full debt redemption."

Business Highlights:

- **Continued Growth Within Key PEDMARK® Accounts**: Adoption continues to accelerate across new and existing accounts, including multiple Adolescent and Young Adult (AYA) patients across several tumor types receiving PEDMARK®. Strong adoption trends reflect growing confidence in PEDMARK®'s clinical value and reinforce its potential to help reshape the standard of care for patients receiving cisplatin-based treatment, demonstrating that the Company's growth strategies are well aligned with market opportunities.

- **Expanded Field Team to Accelerate Growth**: In the fourth quarter, given the positive momentum Fennec observed over 2025, the Company made the strategic decision to further enhance its execution by increasing

its customer facing team to achieve greater reach and frequency with its customers so the organization can ultimately help more cancer patients protect their hearing.

- **New Real-World Data in Adults with Head and Neck Cancer (HNC):** In February 2026, Fennec announced it presented the first new data since the pivotal clinical program at the 2026 Multidisciplinary Head and Neck Cancers Symposium (MHNCS). Findings supporting the potential use of PEDMARK® in adults with head and neck cancers (HNC) were observed in a multi-institutional retrospective review of 15 adults with HNC. The data showed that PEDMARK® could be safely given ≥ six hours after cisplatin dosing and was easy to incorporate into the real-world care plan for adults with HNC. This strict post-cisplatin timing is a validated approach intended to preserve cisplatin antitumor activity and no disruption to curative-intent cisplatin-based treatment delivery was observed as part of the study review.

- **Initiation of Two Institution-Led Clinical Studies**: In December 2025, Fennec announced that City of Hope, a U.S. cancer research and treatment organization, is evaluating PEDMARK® for the prevention of cisplatin-induced ototoxicity (CIO) in adult men with stage II-III metastatic testicular germ cell tumors. In March 2026, Fennec announced that Tampa General Hospital (TGH) Cancer Institute is initiating a study evaluating the real-world clinical utility of PEDMARK® in reducing the risk of ototoxicity in AYA and adult cancer patients receiving cisplatin-based treatment. Additional investigator-initiated studies supporting the use of PEDMARK® in additional tumor types and patient populations, including AYA cancer, have been submitted to Fennec and are currently under review.

- **STS-J01 in Japan:** In December, Fennec announced positive topline results from the investigator-initiated Phase 2/3 STS-J01 clinical trial evaluating PEDMARK® for the reduction of cisplatin-induced ototoxicity in pediatric and adolescent and young adult (AYA) patients with non-metastatic solid tumors in Japan. The results were from the first large-scale pediatric and adolescent and young adults (AYA) trial in Japan and demonstrated that PEDMARK® can protect hearing without compromising cisplatin's efficacy or introducing any concerning side effects. The Company is pursuing registration in Japan and is also exploring partnering or licensing opportunities for PEDMARK®.

Upcoming Events:

- **Piper Sandler Spring Biopharma Symposium:** The management team will host one-on-one investor meetings at the annual Piper Sandler Spring Biopharma Symposium being held April 15–April 16, 2026 at the Convene One Boston Place.

Financial Results for the Fourth Quarter and Full Fiscal Year Ended December 31, 2025

- **Net Product Sales –** For the fourth quarter of 2025, the Company recorded net product sales of $13.8 million compared to $7.9 million in the fourth quarter of 2024, representing an increase of approximately 75%. For the full fiscal year (FY) 2025, the Company recorded net product sales of approximately $44.6 million compared to $29.6 million in 2024, representing an increase of approximately 50%. The increase in net product sales is attributable to growth across both new and existing accounts with notable success in conversion and adherence of PEDMARK® patients.

- **Selling and Marketing Expenses –** The Company recorded $6.1 million in selling and marketing expenses in the fourth quarter of 2025 compared to $3.9 million in the fourth quarter of 2024. The increase in selling and marketing expenses is largely related to increased payroll and additional marketing expenses as we focused on expanding our commercial team and preparing for additional outreach to community oncology centers and the adolescent and young adult (AYA) population. For the FY 2025, the Company recorded $18.6 million in selling and marketing compared to $18.4 million in fiscal year 2024. The year-over-year slight increase is largely related to increased payroll and marketing expenses in the comparable

period offset by the elimination of European expenses after the announcement of the Norgine transaction in March 2024.

- **General and Administrative (G&A) Expenses –** The Company recorded $8.9 million in G&A expenses fourth quarter of 2025 compared to $4.2 million in the fourth quarter of 2024. For the FY 2025, the Company recorded $28.8 million in G&A expenses compared to $23.1 million in fiscal year 2024. G&A expenses increased in both the comparable quarterly and fiscal years due to increased intellectual property-related legal expenses, increased payroll expenses as headcount increased and increased non-cash expenses associated with equity-based remuneration.

- **Cash Position –** Cash and cash equivalents were $36.8 million as of December 31, 2025. For the FY 2025, there was a $10.2 million increase in cash and cash equivalents between December 31, 2024 and December 31, 2025. The net increase in cash was primarily due to the approximately $42.0 million in net proceeds from equity offerings and net cash collected from net product sales offset by operating expenses and the $21.5 million debt paydown in November of 2025. As of December 31, 2025 the company had $0 in debt outstanding.

Fourth Quarter and Full-Year 2025 Conference Call Information

Date: Tuesday, March 24, 2026
Time: 8:30 a.m. Eastern Time
Webcast Link: https://edge.media-server.com/mmc/p/3crq898e
Participant Link: https://register-conf.media-server.com/register/BIb7d9f04377fd4b9cb7b005d167555402

Financial Update

The selected financial data presented below, including results for the three months and year ended December 31, 2025, is derived from our preliminary unaudited consolidated financial results, which have been prepared in accordance with U.S. generally accepted accounting principles. The Company expects to file its Annual Report on Form 10-K for the year ended December 31, 2025, including audited consolidated financial statements and management's discussion and analysis of financial condition and results of operations, shortly with the Securities and Exchange Commission. The Form 10-K will be available at 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, 2025	December 31, 2024	December 31, 2025	December 31, 2024
Revenue				
Product sales, net	$ 13,777	$ 7,925	$ 44,642	$ 29,580
Licensing revenue	—	—	—	17,958
Total revenue	13,777	7,925	44,642	47,538
Operating expenses:				
Cost of product sales	1,764	669	3,764	3,184
Research and development	20	50	250	307
Selling and marketing	6,106	3,944	18,616	18,426
General and administrative	8,903	4,196	28,756	23,053
Total operating expenses	16,793	8,859	51,386	44,970
(Loss) from operations	(3,016)	(934)	(6,744)	2,568
Other (expense)/income				
Realized foreign exchange gain/(loss)	1	(27)	28	(82)
Amortization expense	(27)	(25)	(65)	(89)
Unrealized loss on securities	—	(66)	(2)	(81)
Loss on debt extinguishment	(2,022)	—	(2,022)	—
Interest income	228	399	787	1,682
Interest expense	(308)	(966)	(2,080)	(4,069)
Total other expense/income	(2,128)	(685)	(3,354)	(2,639)
Loss before income tax	(5,144)	(1,619)	(10,098)	(71)
Income tax	—	—	—	(365)
Net loss	$ (5,144)	$ (1,619)	$ (10,098)	$ (436)
Basic net loss per common share	$ (0.17)	$ (0.06)	$ (0.35)	$ (0.02)
Diluted net loss per common share	$ (0.17)	$ (0.06)	$ (0.35)	$ (0.02)
Weighted-average number of common shares outstanding basic	31,175	27,460	28,577	27,294
Weighted-average number of common shares outstanding diluted	31,175	27,460	28,577	27,294

Audited Consolidated Balance Sheets:
(U.S. Dollars in thousands)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 36,788	$ 26,634
Accounts receivable, net	23,221	12,884
Prepaid expenses	3,738	3,080
Inventory	1,565	1,060
Other current assets	1,374	466
Total current assets	66,686	44,124
Non-current assets		
Other non-current assets, net of amortization	3,508	822
Total non-current assets	3,508	822
Total assets	$ 70,194	$ 44,946
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,635	$ 3,241
Accrued liabilities	5,635	3,428
Operating lease liability - current	248	2
Contract liability - current	—	248
Total current liabilities	10,518	6,919
Long term liabilities		
Term loan	—	18,206
PIK interest	—	1,271
Debt discount	—	(139)
Contract liability - long-term	24,561	24,561
Total long term liabilities	24,561	43,899
Total liabilities	35,079	50,818
Commitments and Contingencies		
Shareholders'equity (deficit) :		
Common stock, no par value; unlimited shares authorized; 34,163 shares issued and outstanding (2024 -27,527)	189,906	145,608
Additional paid-in capital	73,745	66,958
Accumulated deficit	(229,779)	(219,681)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' equity (deficit)	35,115	(5,872)
Total liabilities and shareholders' equity (deficit)	$ 70,194	$ 44,946

About Cisplatin-Induced Ototoxicity
Cisplatin and other platinum-based chemotherapies are widely used to treat solid tumors and have been vital in improving survival rates. Unfortunately, these life-saving treatments often result in permanent, irreversible hearing loss, also known as ototoxicity.[i]

Hearing loss from cisplatin treatment is not rare. Studies show that between 60-90% of patients treated with cisplatin may develop hearing loss, depending upon the dose and duration of chemotherapy.[ii] Many of those treated with cisplatin will 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.[iii] Treatment-induced hearing loss can reduce quality of survivorship as it impacts many aspects of life, such as speech and language skills, academic performance, social-emotional development, career potential and the ability to live independently.[iv,v] While audiologic monitoring is recommended to help manage ototoxicity, it is currently underutilized in certain cancer patient populations.

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 1 month of age and older 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 first and only therapeutic agent with proven efficacy and safety data with an established dosing regimen, across two open-label, randomized Phase 3 clinical studies, the Children's Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

Additionally, PEDMARK is recommended for the adolescent and young adult (AYA) population by the National Comprehensive Cancer Network, or NCCN, with a 2A endorsement.

Approximately 500,000 patients in the U.S. are diagnosed annually with cancers that could be treated with a platinum-based chemotherapy.[vi,vii] The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of those treated will require lifelong hearing aids. Until the FDA approval of PEDMARK, there were no preventative agents for this hearing loss. Patients with hearing loss resulting from cancer treatment have a statistically significant worse quality of life compared with peers who have no hearing loss.[viii,ix]

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 committed to the fight against ototoxicity in cancer patients who receive cisplatin-based chemotherapy. Fennec is focused on the commercialization of PEDMARK® to reduce the risk of platinum-induced ototoxicity in cancer patients. PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and United Kingdom (U.K.) approval in October 2023 under the brand name PEDMARQSIÒ.

In March 2024, Fennec entered into an exclusive licensing agreement under which Norgine Pharmaceuticals Ltd., a leading European specialist pharmaceutical company, will commercialize PEDMARQSI® in Europe, U.K., Australia and New Zealand. PEDMARQSI is now commercially available in the U.K. and Germany.

PEDMARK has received Orphan Drug Exclusivity in the U.S. and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection.

For more information, please visit www.fennecpharma.com and follow on LinkedIn.

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®/PEDMARQSI®, the market opportunity for and market impact of PEDMARK®/ PEDMARQSI®, its potential impact on patients and anticipated benefits associated with its use, future commercial and regulatory milestone and royalty payments from Norgine, 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, 2025. 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.

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

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