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, 2019

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	Name of each exchange on which registered
Common Shares, no par value	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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 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, 2019 (the last business day of the Registrant's most recently completed second fiscal quarter) was $45,968,332 based upon a total of 11,492,083 shares held as of June 30, 2019 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 February 11, 2020, there were 19,895,830 shares of the Registrant's Common Shares outstanding.

FENNEC PHARMACEUTICALS INC.

2019 FORM 10-K ANNUAL REPORT

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Our actual results, performance or achievements may be materially different from any results, performance or achievements expressed or implied by such forward-looking statements. Words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," "project," "plan," and other similar words are one way to identify such forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements with respect to (1) our anticipated sources and uses of cash and cash equivalents; (2) our anticipated commencement dates, completion dates and results of clinical trials; (3) our efforts to pursue collaborations with the government, industry groups or other companies; (4) our anticipated progress and costs of our clinical and preclinical research and development programs; (5) our corporate and development strategies; (6) our expected results of operations; (7) our anticipated levels of expenditures; (8) our ability to protect our intellectual property; (9) our ability to fully comply with domestic and international governmental regulation; (10) the anticipated applications and efficacy of our drug candidates; (11) our ability to obtain U.S. Food and Drug Administration ("FDA") and similar foreign approvals for our drug candidate, (12) the nature and scope of potential markets for our drug candidate; (13) future legal liability; and (14) our ability to attract and retain key employees. All statements, other than statements of historical fact, included in this Annual Report that address activities, events or developments that we expect or anticipate will or may occur in the future are forward-looking statements. We include forward-looking statements because we believe that it is important to communicate our expectations to our investors. However, all forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties, including those discussed below in Item 1A., "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are based upon reasonable assumptions, we can give no assurance that our expectations will be attained, and we caution you not to place undue reliance on such statements. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

PART I

Item 1. Business

Fennec Pharmaceuticals Inc. ("Fennec," the "Company," "we," "us," or "our") is a biopharmaceutical company focused on the development of PEDMARK™ (sodium thiosulfate (STS) anhydrous injection)") for the prevention of platinum-induced ototoxicity in pediatric cancer patients. We incorporated under the Canada Business Corporations Act ("CBCA") in September 1996. Effective on August 25, 2011, the Company continued from the CBCA to the Business Corporations Act (British Columbia) (the "Continuance"). We have four wholly-owned subsidiaries: Oxiquant, Inc. and Fennec Pharmaceuticals, Inc., both Delaware corporations, Cadherin Biomedical Inc., a Canadian company, and Fennec Pharmaceuticals (EU) Limited ("Fennec Limited"), an Ireland company. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

Our corporate website is www.fennecpharma.com. We make our periodic and current reports, together with amendments to these reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the 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, or the 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.

Product Candidate - PEDMARK™

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

- PEDMARK™ (sodium thiosulfate (STS) anhydrous injection) –has announced results of two Phase 3 clinical trials for the prevention of cisplatin induced hearing loss, or ototoxicity in children including the pivotal Phase 3 study SIOPEL 6 , "A Multicentre Open Label Randomised Phase 3 Trial of the Efficacy of Sodium Thiosulfate in Reducing Ototoxicity in Patients Receiving Cisplatin Chemotherapy for Standard Risk Hepatoblastoma," and the proof of concept Phase 3 study "A Randomized Phase 3 Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children".

We continue to focus our resources on the development of PEDMARK™.

PEDMARK™

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

Hearing loss among children receiving platinum-based chemotherapy is frequent, permanent and often severely disabling. The incidence of hearing loss in these children depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. In addition, adults undergoing chemotherapy for several common malignancies, including ovarian cancer, testicular cancer, and particularly head and neck cancer and brain cancer, often receive intensive platinum-based therapy and may experience severe, irreversible hearing loss, particularly in the high frequencies.

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

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

In July 2018, the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) accepted our pediatric investigation plan (PIP) for Sodium Thiosulfate for Infusion for the condition of the prevention of platinum-induced ototoxic hearing loss. An accepted PIP is a prerequisite for filing a full Marketing Authorization Application (MAA) for a new medicinal product in Europe. The indication targeted by the Company's PIP is for the prevention of platinum-induced ototoxic hearing loss for standard risk hepatoblastoma (SR-HB). Additional tumor types within the proposed Marketing Authorization (MA) indication will be subject to the Committee for Medicinal Products for Human Use (CHMP) assessment at the time of the MAA. No deferred clinical studies were required in the positive opinion given by PDCO. The Company was also advised that Sodium Thiosulfate for Infusion is eligible for submission of an application for a Pediatric Use Marketing Authorization (PUMA). Therefore, this PIP decision allows Fennec to proceed with the submission of a PUMA in the European Union (EU) with incentives of automatic access to the centralized procedure and up to 10 years of data and market protection. The PUMA is a dedicated MA for new products of medicines previously authorized and no longer under data or marketing protection, covering the indication and appropriate formulation for medicines developed exclusively for use in the pediatric population. In February 2020, Fennec announced that it has submitted a MAA for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. The Company is targeting potential commercial launch of Sodium Thiosulfate for Infusion, if approved, in the first half of 2021.

We initiated our rolling FDA New Drug Application ("NDA") for PEDMARK™ (tradename for Sodium Thiosulfate for Infusion in the US) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors in December 2018. Fennec announced that it has completed its rolling submission of the NDA in February 2020. The Company is targeting a potential commercial launch of PEDMARK™, if approved, in the second half of 2020. In March 2018, PEDMARK™ received Breakthrough Therapy and Fast Track designations from the FDA. Further, PEDMARK™ has received Orphan Drug Designation in the US in this setting.

In September 2019, the Company announced the appointment of Shubh Goel as chief commercial officer. In this newly created position, Ms. Goel will build and oversee Fennec's commercial strategy and organization, including both the launch and commercialization of PEDMARK™, if approved by the FDA and equivalent foreign regulators.

SIOPEL 6

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

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

The primary objectives of SIOPEL 6 were:

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

SIOPEL 6 - Results

Background / Objectives:

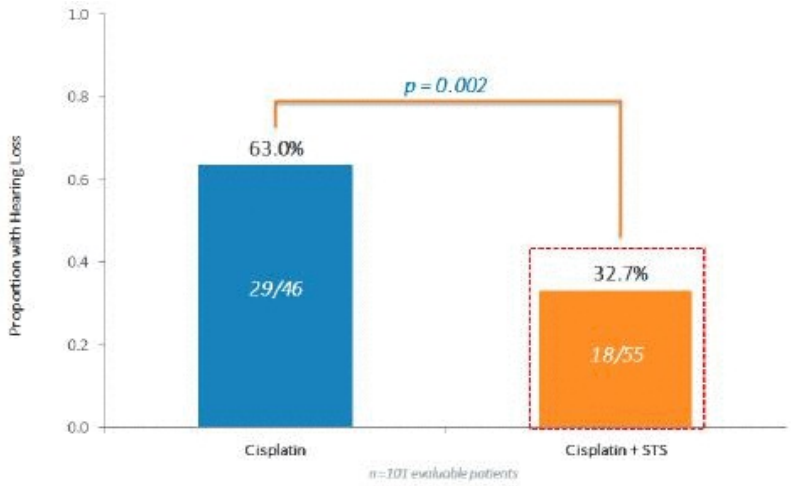
Background: Bilateral high-frequency hearing loss is a serious permanent side-effect of cisplatin therapy, particularly debilitating when occurring in young children. STS has been shown to reduce cisplatin induced hearing loss. SIOPEL 6 was a Phase 3 randomized trial to assess the efficacy of STS in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

Design / Methods:

Methods: Newly diagnosed patients with SR-HB, defined as tumor limited to PRETEXT I, II or III, no portal or hepatic vein involvement, no intra-abdominal extrahepatic disease, AFP >100ng/ml and no metastases, were randomized to Cis or Cis+STS for 4 preoperative and 2 postoperative courses. Cisplatin 80mg/m2 was administered over 6 hours, STS 20g/m2 was administered intravenously over 15 minutes exactly 6 hours after stopping cisplatin. Tumor response was assessed after 2 and 4 preoperative cycles with serum AFP and liver imaging. In case of progressive disease (PD), STS was to be stopped and doxorubicin 60mg/m2 combined with cisplatin. The primary endpoint is centrally reviewed absolute hearing threshold, at the age of ≥3.5 years by pure tone audiometry.

Results:

One hundred and nine randomized patients (52 Cisplatin only ("Cis") and 57 Cis+STS) were evaluable. The combination of Cis+STS was generally well tolerated. With a follow up time of 52 months for the patients the three-year Event Free Survival ("EFS") for Cis is 78.8% Cisplatin and 82.1% for the Cis + STS. The three-year Overall Survival ("OS") is 92.3% for Cis and 98.2% for Cis + STS. Treatment failure defined as Progressive Disease ("PD") at 4 cycles was equivalent in both arms. Among the first 101 evaluable patients, hearing loss occurred in 29/46=63.0% under Cis and in 18/55=32.7% under Cis +STS, corresponding to a relative risk of 0.52(P=0.002).



Conclusions:

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

COG ACCL0431

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

COG ACCL0431 - Results

COG Study ACCL0431, "A Randomized Phase 3 Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children," finished enrollment of 131 patients of which 125 were eligible patients. The patients had been previously diagnosed with childhood cancers.

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

Secondary endpoints included:

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

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

Subjects were randomized either to no treatment (control) or treatment with STS 16 grams/m2 IV over 15 minutes, 6 hours after each cisplatin dose. Hearing was measured using standard audiometry for age and data were reviewed centrally using American Speech-Language-Hearing Association criteria.

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

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

Conclusions:

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

Intellectual Property

Patents are important to developing and protecting our competitive position. Our general policy is to seek patent protection in the United States, major European countries, 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; however, U.S. patents that issue on applications filed before June 8, 1995 may be effective until 17 years from the issue date, if that is later than the twenty-year date. In some cases, the patent term may be extended to recapture a portion of the term lost during the U.S. FDA regulatory review or because of U.S. Patent and Trademark Office, or USPTO, delays in prosecuting the application. The duration of foreign patents varies similarly, in accordance with local law.

Currently, we have licensed from OHSU one U.S. and nine foreign patents. All the patents licensed from OHSU expire in 2021. Additionally, there are two patents pending that we license from OHSU and two additional patents pending owned by Fennec. To the extent the patents owned by Fennec are issued, the Company plans to operate under the owned patents as those licensed from OHSU will expire.

In addition, periods of marketing exclusivity for STS may also be possible in the United States under orphan drug status and in Europe under European Market Exclusivity for Pediatric Use. We obtained U.S. Orphan Drug Designation for the use of STS in the prevention of platinum-induced ototoxicity in pediatric patients in 2004 which provides 7.5 years of market exclusivity upon FDA approval of our NDA. We plan to pursue European Market Exclusivity for Pediatric Use upon approval of the MAA which would allow for 10 years of market exclusivity.

Our success is significantly dependent on our ability to obtain and maintain patent protection for STS, both in the United States and abroad. The patent position of biotechnology and pharmaceutical companies, in general, is highly uncertain and involves complex legal and factual questions, which often results in apparent inconsistencies regarding the breadth of claims allowed and general uncertainty as to their legal interpretation and enforceability. Further, our principal candidate STS, is based on previously known compounds, and the candidates or products that we develop in the future may include or be based on the same or other compounds owned or produced by other parties, some or all of which may not be subject to effective patent protection. In addition, regimens that we may develop for the administration of pharmaceuticals, such as specifications for the frequency, timing and amount of dosages, may not be patentable. Accordingly, our patent applications may not result in patents being issued and issued patents may not afford effective protection. In addition, products or processes that we develop may turn out to be covered by third party patents, in which case we may require a license under such patents if we intend to continue the development of those products or processes.

Our patent position and proprietary rights are subject to certain 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.

Corporate Relationships

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

On May 18, 2015, Fennec negotiated an amendment ("Amendment 1") to the OHSU Agreement, which expands Fennec’s exclusive license to include the use of N-acetylcysteine as a standalone therapy and/or in combination with STS for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments entered in the OHSU Agreement including but not limited to the royalty rate on net sales for licensed products, royalty rate from sublicensing of the licensed technology and the fee payable upon the regulatory approval of a licensed product.

The term of the OHSU Agreement as amended by Amendment 1 expires on the date of the last to expire claim(s) covered in the patents licensed to Fennec or 8 years, whichever is later. In the event a licensed product obtains regulatory approval and is covered by the Orphan Drug Designation, the parties will in good faith amend the term of the agreement. STS is currently protected by methods of use patents that the Company exclusively licensed from OHSU that expire in Europe in 2021 and are currently pending in the United States. The OHSU Agreement is terminable by either Fennec or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. Fennec also has the right to terminate the OHSU Agreement at any time upon 60 days prior written notice and payment of all fees due to OHSU under the OHSU Agreement.

Competition

Competition in the biotechnology and pharmaceutical industries is intense. We expect that if PEDMARK™ achieves 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 any we may develop.

We are aware of a number of companies engaged in the research, development and testing of new cancer therapies or means of increasing the effectiveness of existing therapies, including, among many others, Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, Eisai, Merck KGaA, Novartis, Johnson & Johnson, Pfizer, Roche, Taiho and Sanofi-Aventis. Some of these companies have products that have already received, or are in the process of receiving, regulatory approval or are in later stages of clinical development than our product. Many of them have much greater financial resources than we do. Many of these companies have marketed drugs or are developing targeted cancer therapeutics which, depending upon the mechanism of action of such agents, could be viewed as competitors.

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, for which purpose we are developing STS. 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 STS 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 STS) in experimental systems; and Vitamin E, salicylate and tiopronin, which have all demonstrated moderate activity in rat models to protect against cisplatin-induced ototoxicity, but no clinical trials have been completed and DB-020 a clinical stage candidate in an ongoing Phase1b trial being developed by Decibel Therapeutics. Cochlear implants, which are small electronic devices that are surgically placed in the inner ear to assist with certain types of deafness, are utilized to offer some relief for hearing loss associated with the use of platinum-based anti-cancer agents, but are often suboptimal.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience with preclinical testing and human clinical trials and in obtaining regulatory approvals. In addition, many of the smaller companies that compete with us have formed collaborative relationships with large, established companies to support the research, development, clinical trials and commercialization of any products that they may develop**.** We may rely on third parties to commercialize the products we develop, and our success will depend in large part on the efforts and competitive merit of these collaborative partners. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to PEDMARK™. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our projects. The existence of competitive products, including products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of PEDMARK™.

Government Regulation

The production and manufacture of our product candidate 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 New Drug Application. 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, or 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 "Good Laboratory Practices" as well as "Good Clinical Practices" during clinical testing and "Good Manufacturing Practices" 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 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 New Drug Application 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 Investigational New Drug, (ii) allow further clinical development phases after authorizing a previous phase, or (iii) approve marketing of a drug after the completion of clinical trials.

While European, U.S. and Canadian regulatory systems require that medical products be safe, effective, and manufactured according to high quality standards, the drug approval process in Europe differs from that in the United States and Canada and may require us to perform additional preclinical or clinical testing regardless of whether FDA 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, or 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.

The NDA Approval Process

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA to support approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Fennec anticipates a waiver of the application user fee related to its NDA for PEDMARK ™.

The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit a substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file a decision within 60 days after the original receipt date of the application. If the FDA refuses to file the NDA the applicant may resubmit the NDA with the deficiencies addressed. The resubmitted NDA is considered a new application subject to a new review goal, as described below. If the NDA is refused for filing, the FDA will refund 75 percent of the application fee. Upon resubmission, a new application fee will be required, unless the applicant is eligible for a waiver or reduction. The resubmitted application is also subject to review before the FDA accepts it for filing. Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, and the FDA's commitments under the current PDUFA reauthorization, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications for drugs that are not new molecular entities within ten months from the FDA's receipt of the NDA.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practices (cGMP) requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical investigational sites to evaluate the integrity of the data and confirm compliance with current Good Clinical Practices (cGCP).

After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes the commercial marketing of the drug subject to specific prescribing information for specific indications and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval in its present form. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it wants to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA's determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data.

The FDA also may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, to mitigate any identified or suspected serious risks. The REMS could include a medication guide, physician communication plan, assessment plan and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The drug testing and approval process requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent marketing approval. The FDA may not grant marketing approval on a timely basis, or at all.

Even if the FDA approves a product, it may limit the approved indications for use for the product. The FDA requires that the approved product labeling include information regarding contraindications, warnings or precautions. It may also require that post-approval studies, including a long-term registry, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications or labeling claims or manufacturing changes may be subject to further testing requirements and FDA review and approval. Also after approval, the FDA may require labeling changes as new information becomes known, particularly if new risks are identified, such as unexpected adverse events. The FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-marketing studies and programs or other information that may become known after approval.

Hatch-Waxman Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, amended the U.S. Federal Food, Drug, and Cosmetic Act ("FFDCA") and established abbreviated pathways to market, as well as incentives for the development of new drug products. The Hatch-Waxman Amendments established section 505(b)(2) of the FFDCA that provides an alternative pathway for submission of an NDA, referred to as the 505(b)(2) application, when some or all of the safety and efficacy investigations relied on for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Amendments also established the Abbreviated New Drug Application, or ANDA, approval pathway, which provides an expedient route for generic drugs that have the same active ingredient as a previously approved drug. At the same time, to incentivize continued pharmaceutical innovation, the Hatch-Waxman Amendments authorized periods of statutory exclusivity to protect certain approved new drugs from competition for five or three year periods.

Under the Hatch-Waxman Amendments, a new drug containing an active ingredient that had never before been approved in any other NDA, ANDA, or 505(b)(2) NDA is provided five years of statutory exclusivity upon approval. The FDA refers to this exclusivity as new chemical entity (NCE) exclusivity. During the NCE exclusivity period, the FDA cannot approve an ANDA or a 505(b)(2) application for a drug containing the same active ingredient generally may not be submitted to the FDA. For NCE exclusivity, the FDA regulations interpret "active ingredient" to mean "active moiety," which is defined as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, or other noncovalent derivative of the molecule, responsible for the physiological or pharmacological action of the drug substance." Although the FDA may not approve an ANDA or 505(b)(2) NDA with the same active ingredient during the five-year NCE exclusivity period, an ANDA or 505(b)(2) NDA may be submitted to the FDA after four years if it contains a certification of patent invalidity, non-infringement, or unenforceability.

The Hatch-Waxman Amendments also provide three years of statutory exclusivity for an NDA, a 505(b)(2) NDA, or a supplement to either of these applications for a drug product containing an active moiety that has been previously approved, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application. During this three-year exclusivity period, the FDA will not make effective the approval of any ANDA or 505(b)(2) NDA for the same active moiety for the same conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a new drug containing the same active moiety if it is the subject of a full NDA for which the applicant conducted, sponsored, or obtained a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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 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, or 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 Good Clinical Practices through periodic inspections of trial sponsors, principal investigators and trial sites. If our study sites fail to comply with applicable Good Clinical Practices, 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 products must comply with applicable regulations governing the production of pharmaceutical products known as "Good Manufacturing Practices."

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

Pediatric Marketing Use Authorization
The PUMA approval is typically granted by the European Commission, based on a review by the European Medecines 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 Paediatric 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;
- Are to be exclusively developed for use in children.

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

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

Research and Development

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

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

Research and development expenses totaled $5.6 million and $5.0 million for the fiscal years ended December 31, 2019 and 2018, respectively. We have increased our research and development expenses related to PEDMARK™ as a result of our drug manufacturing activities related to the preparation for registration batches and NDA and MAA submission.

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

Employees

At December 31, 2019, we had four employees (our Chief Executive Officer, Chief Financial Officer, Chief Commercial Officer, and Controller). These employees are employed on a full-time basis and there are no part-time employees. We use independent contractors to perform certain daily operations of the Company.

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 no revenues to date through the sale of our products. 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 had no revenues through the sale of our products, and we do not expect to have significant revenues until we are able to either sell our product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue. We have incurred significant operating losses every year since our inception on September 3, 1996. We reported a loss of approximately $12.8 million for the year ended December 31, 2019 and reported a net loss of approximately $9.9 million (which included a non-cash loss on derivative liabilities of $0.2 million) for the year ended December 31, 2018. At December 31, 2019, we had an accumulated deficit of approximately $144.0 million. We anticipate incurring substantial additional losses due to the need to spend substantial amounts on activities required for regulatory approval of PEDMARK™, commercial launch preparation of PEDMARK™, anticipated research and development activities, and general and administrative expenses, among other factors. We have not commercially introduced any products. Our ability to attain profitability will depend upon our ability to fund and develop products that are safe, effective and commercially viable, to obtain regulatory approval for the manufacture and sale of our product candidate and to license or otherwise market our product candidate successfully. Any revenues generated from such product, assuming it is successfully developed, marketed and sold, may not be realized for a number of years. We may never achieve or sustain profitability on an ongoing basis.

PEDMARK™ is currently our only product candidate 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 generated no revenue from product sales, do not have any products currently available for sale, and none are expected to be commercially available for sale until we have completed regulatory approval of PEDMARK™. PEDMARK™ is currently our only product candidate. 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™ and completed submission of our NDA in the U.S. We anticipate substantial regulatory review prior to the commercialization of PEDMARK™.

We may require additional financing to obtain marketing approval of PEDMARK™ 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 our product development, other operations or commercialization efforts.

Based on available resources, we believe that our cash and cash equivalents of $13.7 million available and the $12.5 million debt facility announced in February 2019 (under which we had not yet made an borrowings) are sufficient to fund our anticipated operating and capital requirements to NDA approval and the commencement of commercialization efforts expected to occur later in 2020, subject to approval of our NDA. Moreover, we expect to continue to incur losses for the foreseeable future as we continue our development of and seek marketing approvals for PEDMARK™. Further, we may not be able to secure NDA approval prior to the expiration of our debt facility in September 2020. 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.

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

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

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

Since we conduct a significant portion of our research and development through collaborations, our success may depend significantly on the performance of such collaborators, as well as any future collaborators. Collaborators might not commit sufficient resources to the research and development or commercialization of our product candidate. Economic or technological advantages of products being developed by others, among other factors, could lead our collaborators to pursue other product candidates or technologies in preference to those being developed in collaboration with us. The commercial potential of, development stage of and projected resources required to develop our drug candidate will affect our ability to maintain current collaborations or establish new collaborators. 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.

Our product candidate is still in development. Due to the long, expensive and unpredictable drug development process, we might not ever successfully develop and commercialize our product candidate.

In order to achieve profitable operations, we, alone or in collaboration with others, must successfully fund, develop, manufacture, introduce and market our product candidate. The time necessary to achieve market success for any individual product is long and uncertain. Our product candidate and research programs are in clinical development and require significant, time-consuming and costly research, testing and regulatory clearances. In developing our product candidate, we are subject to risks of failure that are inherent in the development of therapeutic products based on innovative technologies. The results of preclinical and initial clinical trials are not necessarily predictive of future results. Our product candidate might not be economical to manufacture or market or might not achieve market acceptance. In addition, third parties might hold proprietary rights that preclude us from marketing our product candidate or others might market equivalent or superior products.

We may need to conduct additional human clinical trials to assess our product candidate. If these trials are delayed or are unsuccessful, our development costs will significantly increase, and our business prospects may suffer.

Before obtaining regulatory approvals for the commercial sale of our product candidate, we must demonstrate, through preclinical studies with animals and clinical trials with humans, that our product candidate is safe and effective for use in each target indication. To date, we have performed only limited clinical trials. Much of our testing has been conducted on animals or on human cells in the laboratory, and the benefits of treatment seen in animals or on human cells in a laboratory setting may not ultimately be obtained in human clinical trials. As a result, we may need to perform significant additional research and development activities and conduct extensive preclinical and clinical testing prior to any application for commercial use. We may suffer significant setbacks in additional clinical trials, and the trials may demonstrate our product candidate to be unsafe or ineffective. We may also encounter problems in our clinical trials that will cause us to delay, suspend or terminate those clinical trials, which would increase our development costs and harm our financial results and commercial prospects. Identifying and qualifying patients to participate in clinical trials of our potential products is critically important to our success. The timing of our clinical trials depends on, among other things, the speed at which we can recruit patients to participate in testing our product candidate. We have experienced delays in some of our clinical trials and we may experience significant delays in the future. If patients are unwilling to participate in our trials because of competing clinical trials for similar patient populations, perceived risk or any other reason, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products will be delayed. Other factors that may result in significant delays include obtaining regulatory or ethics review board approvals for proposed trials, reaching agreement on acceptable terms with prospective clinical trial sites, and obtaining sufficient quantities of drugs for use in the clinical trials. Such delays could result in the termination of the clinical trials altogether.

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

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 candidate. 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, 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 might entail ongoing requirements for post-marketing studies. Even if regulatory approval is obtained, 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 current FDA Good Manufacturing Practices 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. If we fail to comply with any of the FDA's continuing regulations, 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 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.

We may be unable to effectively deploy the proceeds from our recent financings for the development of PEDMARK™.

In February 2019, the Company announced a $12.5 million debt facility available to the Company upon approval of PEDMARK™. Any inability on our part to manage effectively the deployment of this capital could limit our ability to successfully develop PEDMARK™. Further, under the terms of the debt facility to be issued we must obtain NDA approval prior to September 30, 2020.

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 develop our product candidate.

The development of our drug candidate 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. STS 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 candidate, or if we infringe upon the intellectual property rights of others, we may not be able to successfully develop and commercialize our product candidate.

The value of our technology 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.

STS is currently protected by methods of use patents that we exclusively licensed from OHSU that expire in Europe and the United States in 2021 and additional patents that are currently pending in the United States. In addition, periods of marketing exclusivity for STS may also be possible in the United States under orphan drug status. We obtained Orphan Drug Designation in the United States for the use of STS in the prevention of platinum-induced ototoxicity in pediatric patients in 2004; if it is subsequently approved, we will have seven and a half years of pediatric exclusivity in the United States from the approval date. Refer to the "Description of Business" section of this Annual Report for a further description of the United States Orphan Drug Designation.

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

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

The vulnerability to off-label use or sale of our product candidate that are covered only by "method of use" patents may cause downward pricing pressure on the product candidate if they are ever commercialized and may make it more difficult for us to enter into collaboration or partnering arrangements for the development of this product candidate.

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

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

We have no 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 candidate, 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. 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 may lack the resources necessary to effectively market our product candidate, and we may need to rely on third parties over whom we have little or no control and who may not perform as expected.

We may not have the necessary resources to market our product candidate. If we develop any products with commercial potential, we will either have to develop a marketing capability, including a sales force, which is difficult and expensive to implement successfully, or attempt to enter into a collaboration, merger, joint venture, license or other arrangement with third parties to provide a substantial portion of the financial and other resources needed to market such products. We may not be able to do so on acceptable terms, if at all. If we rely extensively on third parties to market our products, the commercial success of such products may be largely outside of our control.

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

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

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

Even though we believe we take a conservative approach to investing our funds, the nature of financial markets exposes us to investment risk, including the risks that the value and liquidity of our money market investments 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.

Risks Related to the Clinical Development and Marketing Approval of Our Product Candidate

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

Our current product candidate has not gained marketing approval for sale in the United States or any other country, and we cannot guarantee that we will ever have any marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidate in a timely manner. We cannot commercialize our product candidate in the United States without first obtaining approval from the FDA to market each product candidate. Similarly, we cannot commercialize our product candidate outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Our product candidate could fail to receive marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may find the human subject protections for our clinical trials inadequate and place a clinical hold on an Investigational New Drug Application, or 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;
- the FDA could determine that we cannot rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, for our product candidate;
- we may be unable to demonstrate to the satisfaction of the FDA or 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 or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA could determine that our application relies, or must rely, upon a listed drug or drugs that we a failed to identify or that approval of our 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;
- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an application to obtain marketing approval in the United States or elsewhere;
- the FDA or 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; and
- the approval policies or regulations of the FDA or 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 in the United States, to the satisfaction of the FDA, 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 the United States, it is necessary to submit and obtain approval of a New Drug Application, or 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 Current Good Manufacturing Practice, or cGMP, requirements. 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, and good clinical practice, or cGCP.

Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and reviewed by the FDA, or ultimately be approved. If the application is not accepted for review, the FDA may require that we conduct additional clinical studies or preclinical testing, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA might not consider any additional information to be complete or sufficient to support the filing or approval of the NDA.

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 candidate were to successfully obtain approval from regulatory authorities, 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 candidate may be withdrawn. If we are unable to obtain marketing approval for our product candidate 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 candidate 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 of our current or future product candidates.

Our risk of delay in product approvals is increased if the United States government is fully or partially shut down due to lack of continuity in funding.

Our business operations, and particularly the timing of the outcome of review of our NDA filing for marketing approval of PEDMARK™, are directly and indirectly affected by the operations of the United States government, including but not limited to the FDA. Any interruption in the continuity of funding of all or a part of government activities could have a significant negative effect on our business, including the timing of that review decision. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the United States government has had shut downs. We cannot predict the likelihood, duration, impact, or timing of any future shutdown. There can be no assurance that if such shutdown(s) were to occur in the future, adequate funds would be available to the FDA and other U.S. government agencies to allow them to continue their activities uninterrupted. Even when funding is restored following one or more shutdowns, we cannot predict the ongoing impact of such shutdowns on our business, or the degree to which funding would be restored to the FDA or other agencies having an impact on our business.

If we are unable to submit an application for approval under Section 505(b)(2) of the FFDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current strategy for seeking marketing authorization in the United States for our product candidate relies primarily on Section 505(b)(2) of the FFDCA, which permits use of a marketing application, referred to as a 505(b)(2) application, 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 or use. The FDA interprets this to mean that an applicant may rely for approval on such data as that found in published literature or the FDA's finding of safety or effectiveness, or both, of a previously approved drug product owned by a third party. There is no assurance that the FDA would find the published literature or third-party data relied upon by us in a 505(b)(2) application sufficient or adequate to support approval, and the FDA may require us to generate additional data to support the safety and efficacy of our product candidate. Consequently, we may need to conduct substantial new research and development activities beyond those we currently plan to conduct. Such additional new research and development activities would be costly and time-consuming and there is no assurance that such data generated from such additional activities would be sufficient to obtain approval.

If the data to be relied upon in a 505(b)(2) application are related to drug products previously approved by the FDA and covered by patents that are listed in the FDA's Orange Book, we would be required to submit with our 505(b)(2) application an appropriate patent certification or statement. The type of patent certification that would enable us to obtain approval of our application before a listed patent expires, known as a Paragraph IV Certification, would require us to certify that we do not infringe the listed patent or that such patent is invalid or unenforceable. We would be required to provide timely notice to the patent owner and the holder of the approved NDA. If a patent infringement action is initiated against us within 45 days from receipt of our Paragraph IV Certification, the approval of our NDA would be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidate under Section 505(b)(2) may, therefore, be delayed until patent exclusivity expires or until we successfully challenge those patents. Alternatively, we may elect to generate sufficient clinical data so that we would no longer need to rely on third-party data, which would be costly and time-consuming and there would be no assurance that such data generated from such additional activities would be sufficient to obtain approval.

We may not be able to obtain shortened review of our applications, and the FDA may not agree that our product candidate qualifies for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet anticipated or reasonable development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our product candidate. If the FDA changes its interpretation of Section 505(b)(2) allowing reliance on data in published literature or a previously approved drug application owned by a third party, or there is a change in the law affecting Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

Even if we receive marketing approval for our product candidate, such approved products will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidate, if approved, 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 products.

If the FDA approves any of our product candidate, 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 GCP 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 policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval, manufacturing or commercialization of our product candidate. 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 our current product candidate 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™, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling, known as "off-label" use, nor may it be promoted prior to obtaining marketing approval. If we receive marketing approval for our product candidate for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label if the physicians personally believe in their professional medical judgment it could be used in such manner. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, the FDA requires that promotional claims not be "false or misleading" as such terms are defined in the FDA's regulations. For example, the FDA requires substantial evidence, which generally consists of two adequate and well-controlled head-to-head clinical trials, for a company to make a claim that its product is superior to another product in terms of safety or effectiveness. Generally, unless we perform clinical trials meeting that standard comparing our product candidate to competitive products and these claims are approved in our product labeling, we will not be able promote our current product candidate 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 any drug candidates for which we obtain 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 any drug candidates for which we obtain marketing approval. 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 our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

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, as evidenced by the enactment in the United States of the Affordable Care Act. Among other things, the Affordable Care Act contains 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 the Affordable Care Act, as well as other 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 any approved 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 any drug products for which we may obtain marketing approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a 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 candidate 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.

Risks Related to Commercialization of Our Product Candidate

Even if we obtain the required regulatory approvals in the United States and other territories, the commercial success of our product candidate will depend on market awareness and acceptance of our product candidates.

Even if we obtain marketing approval for PEDMARK™ or any other product candidate that we may develop or acquire in the future, the products may not gain market acceptance among physicians, key opinion leaders, healthcare payors, patients and the medical community. Market acceptance of any approved products depends on a number of factors, including:

- the timing of market introduction;
- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product 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 the product 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. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are 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 candidates are smaller than we believe they are, then our revenues may be adversely affected, and our business may suffer.

The market opportunities that our current and future product candidates are 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 candidates, 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 candidates.

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

There is significant uncertainty related to third-party coverage and reimbursement of newly approved pharmaceuticals. Market acceptance and sales of our product candidate, should it receive marketing approval, 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 any product that we commercialize 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, any drug candidate for which we obtain marketing approval.

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 products 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 any of our product candidate. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. 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 products to be cost-effective compared to other available therapies, they may not cover the products for which we receive FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products 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 one or more products for which we receive marketing approval, 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 before, or 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 candidate for the treatment of orphan and ultra-orphan diseases for which there is a small patient population in the United States. 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 candidate obsolete. As a result of all of these factors, maintaining Orphan Drug designation for our product candidate is essential to our viability since our competitors may, among other things:

- have greater name and brand recognition, financial 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 obtain Orphan Drug designation as well as:

- our ability to design and successfully execute appropriate clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the results of our clinical trials and the efficacy and safety of our product candidate;
- the speed at which we develop our product candidate;
- 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 candidate;
- our ability to commercialize and market any of our product candidate if it obtains marketing approval;
- our ability to manufacture and sell commercial quantities of any approved our product candidate;
- acceptance of our product candidate by physicians, other healthcare providers and patients; and
- the cost of treatment in relation to alternative therapies.

If our competitors are able to obtain orphan drug exclusivity for their products that are for the same indication as our product candidate, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time or benefit from that exclusivity.

We have orphan drug designation in the United States for PEDMARK™ for the prevention of platinum induced ototoxicity in pediatric patients.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, that product is entitled to a period of marketing exclusivity, which precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven and a half years in the United States. Maintaining orphan drug designation for PEDMARK™ may be important to its success. Even with orphan drug designation, we may not be able to maintain it. For example, if a competitive product that treats the same disease as our product candidate is shown to be clinically superior to our product candidate, any orphan drug designation we have obtained will not block the approval of such competitive product and we may effectively lose what had previously been orphan drug designation. Orphan drug designation for PEDMARK™ also will not bar the FDA from approving another STS drug product for another indication. In the United States, reforms to the Orphan Drug Act, if enacted, could also materially affect our ability to maintain orphan drug designation for PEDMARK™ for cisplatin induced ototoxicity in pediatric cancer.

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 candidate 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 products 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 products 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 candidate may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidate is rendered obsolete by advancements in pharmaceutical technologies, our prospects will suffer.

Government controls and healthcare reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of healthcare. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of any product candidate to other available therapies. If reimbursement of any product candidate is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability in such country. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for our product candidate under a Part D prescription drug plan will likely be lower than the prices that might otherwise be obtained outside of the Medicare Part D prescription drug plan. Moreover, while Medicare Part D applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any product candidate. Among policy-makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. 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 any product candidate; the ability to set a price that we believe is fair for any product candidate; our ability to generate revenues and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

We have limited experience as a company in marketing or distributing pharmaceutical products. If we are unable to expand our marketing capabilities and effectively commercialize PEDMARK™, our business, results of operations and financial condition may be materially adversely affected.

Our strategy is to build our sales, marketing and distribution capabilities to successfully commercialize PEDMARK™ in the United States and evaluate commercial opportunities globally for PEDMARK™. While we have begun to establish our commercial team, we have limited experience commercializing pharmaceutical products as an organization. In order to successfully market PEDMARK™, we must continue to build our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize PEDMARK™ and may not become profitable.

Included in our strategy in the United States is to have a sales force to commercialize PEDMARK™, subject to it receiving marketing approval . These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capability. We will need to train our sales force to ensure that a consistent and appropriate message about PEDMARK™ is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of PEDMARK™ and its proper administration, all while maintaining compliance with regulatory requirements, our efforts to successfully commercialize PEDMARK™ could be harmed, which would negatively impact our ability to generate product revenue. Additionally, we will need to maintain and further develop our sales force to achieve commercial success, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to continue to develop and effectively maintain our commercial team, our ability to successfully commercialize PEDMARK™ would be limited, and we would not be able to generate product revenue successfully.

There are risks involved both with establishing our own sales and marketing capabilities, and with entering into arrangements with third parties to perform these services. For example, any efforts to develop 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, if 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 products 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 products 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 products. 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.

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 products. 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. Our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our current drug candidates, or any potential future products we may acquire and use in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, 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 Third Parties

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

We do not currently own or operate manufacturing facilities for clinical or commercial production of our product candidate. We lack the resources and the capability to manufacture any of our product candidate 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 candidate 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 candidate 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 candidate than potentially would be the case if we were to manufacture our product candidate. 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 candidate. 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.

The facilities used by our current contract manufacturers and any future manufacturers to manufacture our product candidate must be inspected by the FDA during the review of our NDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, the FDA may refuse to approve our NDA. If the FDA or a comparable foreign regulatory authority does not approve our NDA because of concerns about the manufacture of our product candidate or if significant manufacturing issues arise in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop our product candidate, to obtain marketing approval of our NDA or to continue to market our product candidate, if approved. Although we are ultimately responsible for ensuring compliance with these regulatory requirements, we do not have day-to-day control over a contract manufacturing organization ("CMO") or other third-party manufacturer's compliance with applicable laws and regulations, including cGMPs and other laws and regulations, such as those related to environmental health and safety matters. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidate or that obtained approvals could be revoked, which would adversely affect our business and reputation. In addition, third-party contractors, such as our CMOs, may elect not to continue to work with us due to factors beyond our control. Although we have contracts in place, they may also refuse to work with us because of their own financial difficulties, business priorities or other reasons, at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

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. However, making this change may be costly and may delay clinical trials. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture our drug candidates 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 candidate. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, it may cause delays in commencing and completing clinical trials of our product candidate or we may be unable to obtain marketing approval for or commercialize our product candidate.

Clinical trials must meet applicable FDA and foreign regulatory requirements. We do not have the ability to independently conduct clinical trials for our product candidate. 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 candidate; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the FDA and other foreign regulatory authorities require us to comply with IND and human subject protection regulations and current good clinical practice standards, commonly referred to as GCPs, 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 GCPs 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 GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable 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 GCPs. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

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

Risks Related to Our Intellectual Property

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

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

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

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

While we are not currently aware of any third-party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our products 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 the affected products 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.

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 a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. 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 candidate.

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 candidate, 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, product candidate and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product candidate, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidate 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 any of our product candidate, our ability to develop and commercialize those product candidate 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 candidate will be eligible to be listed in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any patents issued to us or our licensors and collaborators will provide us with any competitive advantages, or will be challenge by third parties;
- we will develop additional proprietary technologies that are patentable;
- the United States government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or
- our business may infringe the patents or other proprietary rights of others.

The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patents and our financial ability to enforce our patents and other intellectual property. Our ability to maintain and solidify our proprietary position for our products 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. Due to the extensive amount of time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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 candidate 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 candidate 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.

The patent protection for our product candidate 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 candidate 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 candidate, 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 candidate.

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 candidate, 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 our licensor 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 the patents we license at risk of being invalidated or interpreted narrowly and could put 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 prevent us from developing or commercializing our product candidate.

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 candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidate 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 candidate 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 candidate or the use or manufacture of our product candidate. 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, limiting our ability to develop our product candidate, 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 the applicable product candidate 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 a 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 one or more of our product candidate. 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 bring our product candidate to market.

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

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 candidate 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 candidate 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 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 candidate. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidate, 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 candidate. 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 candidate, 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

If we are unable to obtain applicable U.S. and/or foreign regulatory approvals, we will be unable to develop and commercialize our drug candidate.

The preclinical studies and clinical trials of our product candidate, as well as the manufacturing, labeling, sale and distribution, export or import, marketing, advertising and promotion of our product candidate, are subject to various regulatory frameworks in the United States, Canada and other countries. Any products that we develop must receive all relevant regulatory approvals and clearances before any marketing, sale or distribution. The regulatory process, which includes extensive preclinical studies and clinical testing to establish product safety and efficacy, can take many years and cost substantial amounts of money. As a result of the length of time, many challenges and costs are associated with the drug development process, and the historical rate of failures for drug candidates is extremely high. Changes in regulatory policy could also cause delays or affect regulatory approval. Any regulatory delays may increase our development costs and negatively impact our competitiveness and prospects. It is possible that we may not be able to obtain regulatory approval of our drug candidate or approvals may take longer and cost more to obtain than expected.

Regulatory approvals, if granted, may entail limitations on the uses for which any product we develop may be marketed, limiting the potential sales for any such products. The granting of product approvals can be withdrawn at any time, and manufacturers of approved products are subject to regular reviews, including for compliance with FDA Good Manufacturing Practices regulations. Failure to comply with any applicable regulatory requirement, which may change from time to time, can result in warning letters, fines, sanctions, penalties, recalling or seizing products, suspension of production, or even criminal prosecution.

Future sales of our product candidate may suffer if it fails to achieve market acceptance.

Even if our product candidate is successfully developed and achieves appropriate regulatory approval, it may not enjoy commercial acceptance or success. Our product candidate may compete with a number of new and traditional drugs and therapies developed by major pharmaceutical and biotechnology companies. Market acceptance is dependent on the product candidate demonstrating clinical efficacy and safety, as well as demonstrating advantages over alternative treatment methods. In addition, market acceptance is influenced by government reimbursement policies and the ability of third parties to pay for such products. Physicians, patients, or the medical community may not accept or utilize any products we may develop.

We face a strong competitive environment. Other companies may develop or commercialize more effective or cheaper products, which may reduce or eliminate the demand for our product candidate.

The biotechnology and pharmaceutical industry, and in particular the field of cancer therapeutics where we are focused, is very competitive. Many companies and research organizations are engaged in the research, development and testing of new cancer therapies or means of increasing the effectiveness of existing therapies, including, among many others, Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, Eisai, Merck KGaA, Novartis, Johnson & Johnson, Pfizer, Roche, Taiho and Sanofi-Aventis. Many of these companies have marketed drugs or are developing targeted cancer therapeutics, which depending upon the mechanism of action of such agents could be competitors.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience with preclinical testing and human clinical trials and in obtaining regulatory approvals. Also, some of the smaller companies that compete with us have formed collaborative relationships with large, established companies to support the research, development, clinical trials and commercialization of any products that they may develop. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to those we seek to develop. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our projects.

We are likely to face competition in the areas of product efficacy and safety, ease of use and adaptability, as well as pricing, product acceptance, regulatory approvals and intellectual property. Competitors could develop more effective, safer and more affordable products than we do, and they may obtain patent protection or product commercialization before we do or even render our product candidate obsolete. The existence of competitive products, including products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of any product that we develop.

We may face product liability claims that could require us to defend costly lawsuits or incur substantial liabilities that could adversely impact our financial condition, receipt of regulatory approvals for our product candidate and our results of operation.

The use of our product candidate in clinical trials and for commercial applications, if any, may expose us to liability claims in the event that such product candidate causes injury or death or results in other adverse effects. These claims could be made by health care institutions, contract laboratories, and subjects participating in our clinical studies, patients or others using our product candidate. In addition to liability claims, certain serious adverse events could require interruption, delay and/or discontinuation of a clinical trial and potentially prevent further development of our product candidate. Litigation is very expensive, even if we defend successfully against possible litigation. In addition, our existing insurance coverage may not be adequate to cover certain types or amounts of liability, and future coverage may not be available in sufficient amounts or at reasonable cost. Further, it is possible that we may later reduce or terminate this coverage based on future availability of financial resources. Adverse liability claims may also harm our ability to obtain or maintain regulatory approvals.

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 outsources, dies 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 commercialization of our product candidate.

If our product candidate achieves regulatory approval, we may be materially adversely affected by the continuing efforts of governmental and third-party payers to contain or reduce health care costs. For example, if we succeed in bringing one or more products to market, such products may not be considered cost-effective and the availability of consumer reimbursement may not exist or be sufficient to allow the sale of such products on a competitive basis. 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 candidate.

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 candidate.

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 products.

Since its enactment, there have been judicial and Congressional challenges to numerous aspects of the Affordable Care Act, and Congress and the executive branch are seeking to replace the Affordable Care Act with new federal legislation. 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 candidate, 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 candidate 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 stock 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 OTCQB 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 March 11, 2013 to February 11, 2020, the closing trading price of our stock fluctuated from a high of $18.45 Canadian dollars ("CAD") per share to a low of CAD$0.72 per share on the TSX. From September 13, 2017 to February 11, 2020, 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 development of our sole product candidate, PEDMARK™;
- the need to raise additional capital and the terms of any transaction we are able to enter into;
- other external factors generally or stock market trends in the pharmaceutical or biotechnology industries specifically;
- announcements of licensing agreements, joint ventures, collaborations or other strategic alliances that involve our product or those of our competitors;
- innovations related to our or our competitors' products;
- actual or potential clinical trial results related to our or our competitors' products;
- the status, timing and outcome of regulatory approvals;
- our financial results or those of our competitors;
- reports of securities analysts regarding us or our competitors;
- developments or disputes concerning our licensed or owned patents or those of our competitors;
- developments with respect to the efficacy or safety of our product or those of our competitors; and
- health care reforms and reimbursement policy changes nationally and internationally.

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

At February 11, 2020, our current shareholders separately representing more than 5% ownership in our Company collectively represented beneficial ownership of approximately 41.86% of our common shares. In particular, Southpoint Capital Advisors LP ("Southpoint Capital") owns or exercises control over approximately 4.0 million common shares, representing approximately 20.1% of our issued and outstanding common shares; Essetifin SpA, owns approximately 3.2 million shares, or approximately 16.2% of our issued and outstanding common shares; and venBio owns approximately 1.1 million shares, or approximately 5.6% of our issued and outstanding common shares. Southpoint Capital, Essetifin SpA, venBio, 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 February 11, 2020, we had outstanding warrants to purchase approximately 0.04 million shares of our common shares at an exercise price of $6.80 per common share. In addition, at February 11, 2020, there were approximately 3.1 million common shares issuable upon the exercise of outstanding stock options, of which options to purchase approximately $1.2 million were denominated in Canadian dollars and had a weighted average exercise price of CAD $2.43 per common share and options to purchase approximately $9.9 million were denominated in U.S. dollars and had a weighted average exercise price of $4.05 per common share. We may also issue further warrants as part of any future financings in addition to the additional 1.9 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 develop our product, we may need to raise additional funds through either the sale of additional equity, the issue 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 continue the development of our drug candidate PEDMARK™, to seek regulatory approval for PEDMARK™, and to invest in precommercial activities for PEDMARK™. 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 development of our product candidate 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. Moreover, 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. We urge U.S. investors to consult their own tax advisors regarding the possible application of the PFIC rules. 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—General Rules Applicable to the Ownership and Disposition of Common Shares." This paragraph is qualified in its entirety by the discussion below under the heading "Material U.S. Federal Income Tax Considerations." 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, and our per share price may be adversely affected.

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 internal control over financial reporting was effective as of December 31, 2019. 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.

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have an operating lease in Research Triangle Park, North Carolina utilizing small space within a commercial building. The operating lease has payments of $200 per month with no scheduled increases. This operating lease is terminable with 30 days' notice and has no penalties or contingent payments due.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer's 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". Prior to September 13, 2017, our common shares traded in the U.S. on the OTCQB Market under the trading symbol "FENCF". The following table sets forth the quarterly high and low market closing prices, and average daily trading volume on the OTCQB, Nasdaq Capital Market (as applicable), and the TSX, for the two most recent full fiscal years:

	Nasdaq Capital Market/OTCQB (in U.S. dollars)			Toronto Stock Exchange (in Canadian dollars)		
Fiscal 2019:	High $	Low $	Volume	High $	Low $	Volume
Quarter ended 12/31/19	$ 6.49	$ 4.25	30,248	$ 8.45	$ 5.65	321
Quarter ended 09/30/19	4.95	3.85	34,336	6.55	5.00	489
Quarter ended 06/30/19	5.09	3.30	107,826	6.80	4.38	1,622
Quarter ended 03/31/19	$ 7.58	$ 4.64	45,072	$ 10.00	$ 6.22	1,502
Fiscal 2018:	High $	Low $	Volume	High $	Low $	Volume
Quarter ended 12/31/18	$ 8.39	$ 5.37	80,832	$ 10.72	$ 7.22	2,062
Quarter ended 09/30/18	10.83	7.84	84,521	14.16	10.19	1,911
Quarter ended 06/30/18	14.33	10.05	109,447	18.45	13.28	4,109
Quarter ended 03/31/18	$ 12.10	$ 8.26	44,777	$ 15.65	$ 10.36	1,629

As of February 11, 2020, the last reported sale on the TSX was CAD$9.55 per share and the last reported sale on the Nasdaq Capital Market was $7.17 per share.

Record Holders

As of February 11, 2020, there were approximately 38 shareholders of record of our common shares, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC, and one of which was The Canadian Depository for Securities Limited, or 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. 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 is a general summary of certain U.S. federal income tax considerations applicable to a U.S. Holder (as defined below) arising from and relating to the acquisition, ownership, and disposition of our common shares. This summary is for general information purposes only and does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Holder arising from and relating to the acquisition, ownership, and disposition of our common shares. In addition, this summary does not take into account the individual facts and circumstances of any particular U.S. Holder that may affect the U.S. federal income tax consequences to such U.S. Holder, including, without limitation, specific tax consequences to a U.S. Holder 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 the U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences to U.S. Holders of the acquisition, ownership, and disposition of our common shares. In addition, except as specifically set forth below, this summary does not discuss applicable tax reporting requirements. Each prospective U.S. Holder should consult its own tax advisors regarding the U.S. federal, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences relating to the acquisition, ownership and disposition of our common shares.

No legal opinion from U.S. legal counsel or ruling from the IRS has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary. In addition, because the authorities on which this summary is based are subject to various interpretations, the IRS and the U.S. courts could disagree with one or more of the conclusions described in this summary.

General

Authorities

This summary is based on the Code, Treasury Regulations (whether final, temporary, or proposed), published rulings of the IRS, published administrative positions of the IRS, 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 U.S. court decisions that are applicable, and, in each case, as in effect and available, as of the date of this document. Any of the authorities on which this summary is based could be changed in a material and adverse manner at any time, and any such change could be applied retroactively. 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 our 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 of our common shares. 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.

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 our common shares as part of a straddle, hedging transaction, conversion transaction, constructive sale, or other arrangement involving more than one position;
- acquired our common shares in connection with the exercise of employee stock options or otherwise as compensation for services;
- hold our 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 or former 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 our 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 our 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

A U.S. Holder that receives a distribution, including a constructive distribution, with respect to a common share will be required to include the amount of such distribution in gross income as a dividend (without reduction for any Canadian income tax withheld from such distribution) to the extent of our current and accumulated "earnings and profits," as computed for U.S. federal income tax purposes. A dividend generally will be taxed to a U.S. Holder at ordinary income tax rates. (See, however, the exception discussed below for individual and other non-corporate U.S. Holders, which may allow such holders preferential rates when we have terminated PFIC status.) To the extent that a distribution exceeds our current and accumulated "earnings and profits," such distribution will be treated, first, as a tax-free return of capital to the extent of a U.S. Holder's tax basis in our common shares and thereafter as gain from the sale or exchange of such common shares. However, we may not maintain the calculations of our earnings and profits in accordance with U.S. federal income tax principles, and U.S. Holders may have to assume that any distribution by us with respect to our common shares will constitute ordinary dividend income. Dividends received on our common shares by corporate U.S. Holders generally will not be eligible for the "dividends received deduction." Provided that (1) we are eligible for the benefits of the Canada-U.S. Tax Convention or (2) our common shares are readily tradable on a United States securities market (and certain holding period and other conditions are satisfied), dividends paid by us to non-corporate U.S. Holders, including individuals, will be eligible for the preferential tax rates applicable to long-term capital gains for dividends unless we are classified as a PFIC in the tax year of distribution or in the preceding tax year. The dividend rules are complex, and each U.S. Holder should consult its own tax advisors regarding the application of such rules.

Upon the sale or other taxable disposition of our common shares, subject to the PFIC rules below, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the U.S. dollar value of cash received plus the fair market value of any property received and such U.S. Holder's tax basis in such common shares sold or otherwise disposed of. A U.S. Holder's tax basis in our common shares generally will be determined initially by the holder's U.S. dollar cost for our common shares (with adjustments provided under the PFIC rules below). Subject again to the PFIC rules, 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, our 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 U.S. Holder that is a corporation. Deductions for capital losses are subject to significant limitations under the Code. If we are determined to be a PFIC, any gain realized on our common shares could be ordinary income under the rules discussed below.

PFIC Status of the Company

If we were to constitute a "passive foreign investment company" under the meaning of Section 1297 of the Code (a "PFIC") for any taxable year during a U.S. Holder's holding period, then certain potentially adverse rules may affect the U.S. federal income tax consequences to a U.S. Holder as a result of the acquisition, ownership and disposition of our common shares. 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. No opinion of legal counsel or ruling from the IRS concerning our status as a PFIC has been obtained or is currently planned to be requested. The determination of whether any corporation was, or will be, a PFIC for a tax year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any tax year depends on the assets and income of such corporation over the course of each such tax year and, as a result, cannot be predicted with certainty as of the date of this Annual Report. Accordingly, there can be no assurance that the IRS will not challenge any determination made by us (or any of our subsidiaries) concerning our PFIC status in any taxable year. Each U.S. Holder should consult its own tax advisors regarding the PFIC status of us and our subsidiaries.

In any taxable year in which we are classified as a PFIC, a U.S. Holder will be required to file an annual report with the IRS containing such information as Treasury Regulations and/or other IRS guidance may require. IRS Form 8621 is currently used for such filings. In addition to penalties, a failure to satisfy such reporting requirements may result in an extension of the time period during which the IRS can assess a tax. U.S. Holders should consult their own tax advisors regarding the requirements of filing such information returns under these rules, including the requirement to file an IRS Form 8621 annually.

We generally will be a PFIC for a taxable year if, for such year, (a) 75% or more of our gross income is passive income (the "PFIC income test") or (b) 50% or more of the value of our assets either produce passive income or are held for the production of passive income, based on the quarterly average of the fair market value of such assets (the "PFIC asset test"). "Gross income" generally includes all sales revenues less the cost of goods sold, plus income from investments and from incidental or outside operations or sources, and "passive income" generally includes, for example, dividends, interest, certain rents and royalties, certain gains from the sale of stock and securities, and certain gains from commodities transactions.

Active business gains arising from the sale of commodities generally are excluded from passive income if substantially all (85% or more) of a foreign corporation's commodities are stock in trade or inventory, depreciable property used in a trade or business, or supplies regularly used or consumed in the ordinary course of its trade or business, and certain other requirements are satisfied.

For purposes of the PFIC income test and PFIC asset test described above, if we own, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, we will be treated as if we (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. In addition, for purposes of the PFIC income test and PFIC asset test described above, and assuming certain other requirements are met, "passive income" does not include certain interest, dividends, rents, or royalties that are received or accrued by us from certain "related persons" (as defined in Section 954(d)(3) of the Code) also organized in Canada, to the extent such items are properly allocable to the income of such related person that is neither passive income nor income connected with a U.S. trade or business.

Under certain attribution rules, if we are a PFIC, U.S. Holders will generally be deemed to own their proportionate share of our direct or indirect equity interest in any company that is also a PFIC (a ''Subsidiary PFIC''), and will generally be subject to U.S. federal income tax on their proportionate share of (a) any "excess distributions," as described below, on the stock of a Subsidiary PFIC and (b) a disposition or deemed disposition of the stock of a Subsidiary PFIC by us or another Subsidiary PFIC, both as if such U.S. Holders directly held the shares of such Subsidiary PFIC. In addition, U.S. Holders may be subject to U.S. federal income tax on any indirect gain realized on the stock of a Subsidiary PFIC on the sale or disposition of our common shares. Accordingly, U.S. Holders should be aware that they could be subject to tax under the PFIC rules even if no distributions are received on our common shares and no redemptions or other dispositions of our common shares are made.

Default PFIC Rules Under Section 1291 of the Code

If we are a PFIC for any tax year during which a U.S. Holder owns our common shares, the U.S. federal income tax consequences to such U.S. Holder of the acquisition, ownership, and disposition of our common shares will depend on whether and when such U.S. Holder makes an election to treat us and each Subsidiary PFIC, if any, as a "qualified electing fund" or "QEF" under Section 1295 of the Code (a "QEF Election") or makes a mark-to-market election under Section 1296 of the Code (a "Mark-to-Market Election"). A U.S. Holder that does not make either a QEF Election or a Mark-to-Market Election will be referred to in this summary as a "Non-Electing U.S. Holder."

A Non-Electing U.S. Holder will be subject to the rules of Section 1291 of the Code (described below) with respect to (a) any gain recognized on the sale or other taxable disposition of our common shares and (b) any "excess distribution" received on our common shares. A distribution generally will be an "excess distribution" to the extent that such distribution (together with all other distributions received in the current tax year) exceeds 125% of the average distributions received during the three preceding tax years (or during a U.S. Holder's holding period for our common shares, if shorter).

Under Section 1291 of the Code, any gain recognized on the sale or other taxable disposition of our common shares (including an indirect disposition of the stock of any Subsidiary PFIC), and any "excess distribution" received on our common shares or deemed received with respect to the stock of a Subsidiary PFIC, must be ratably allocated to each day in a Non-Electing U.S. Holder's holding period for the respective common shares. The amount of any such gain or excess distribution allocated to the tax year of disposition or distribution of the excess distribution, or allocated to years before the entity became a PFIC, if any, would be taxed as ordinary income at the rates applicable for such year (and not eligible for certain preferred rates). The amounts allocated to any other tax year would be subject to U.S. federal income tax at the highest tax rate applicable to ordinary income in each such year. In addition, an interest charge would be imposed on the tax liability for each such year, calculated as if such tax liability had been due in each such year. A Non-Electing U.S. Holder that is not a corporation must treat any such interest paid as "personal interest," which is not deductible.

If we are a PFIC for any tax year during which a Non-Electing U.S. Holder holds our common shares, we will continue to be treated as a PFIC with respect to such Non-Electing U.S. Holder, regardless of whether we cease to be a PFIC in one or more subsequent tax years. A Non-Electing U.S. Holder may terminate this deemed PFIC status by electing to recognize gain (which will be taxed under the rules of Section 1291 of the Code discussed above), but not loss, as if such common shares were sold on the last day of the last tax year for which we were a PFIC.

QEF Election

A U.S. Holder that makes a timely and effective QEF Election for the tax year in which the holding period of our common shares begins generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to such common shares. A U.S. Holder that makes such a QEF Election will be subject to U.S. federal income tax on such U.S. Holder's pro rata share (based on its ownership of our common shares) of (a) the net capital gain of the Company, which will be taxed as long-term capital gain to such U.S. Holder, and (b) the ordinary earnings of the Company, which will be taxed as ordinary income to such U.S. Holder. Generally, "net capital gain" is the excess of (a) net long-term capital gain over (b) net short-term capital loss, and "ordinary earnings" are the excess of (a) "earnings and profits" over (b) net capital gain. A U.S. Holder that makes a QEF Election will be subject to U.S. federal income tax on such amounts for each tax year in which the Company is a PFIC, regardless of whether such amounts are actually distributed by us to such U.S. Holder. However, for any tax year in which we are a PFIC and has no net income or gain, U.S. Holders that have made a QEF Election would not have any income inclusions as a result of the QEF Election. If a U.S. Holder that made a QEF Election has an income inclusion, such a U.S. Holder may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If such U.S. Holder is not a corporation, any such interest paid will be treated as "personal interest," which is not deductible.

A U.S. Holder that makes a timely and effective QEF Election with respect to the Company generally (a) may receive a tax-free distribution from the Company to the extent that such distribution represents "earnings and profits" of the Company that were previously included in income by the U.S. Holder because of such QEF Election and (b) will adjust such U.S. Holder's tax basis in our common shares to reflect the amount included in income or allowed as a tax-free distribution because of such QEF Election. A U.S. Holder that makes a QEF Election generally will recognize capital gain or loss on the sale or other taxable disposition of our common shares.

A U.S. Holder may make a timely QEF Election by filing the appropriate QEF Election documents (currently IRS Form 8621) at the time such U.S. Holder files a U.S. federal income tax return for such year. If a U.S. Holder does not make a timely QEF Election for the first year in the U.S. Holder's holding period in which we are a PFIC, the U.S. Holder may still be able to make an effective QEF Election in a subsequent year if such U.S. Holder meets certain requirements and makes a "purging" election to recognize gain (which will be taxed under the rules of Section 1291 of the Code discussed above) as if such common shares were sold for their fair market value on the day the QEF Election is effective. If a U.S. Holder makes a QEF Election but does not make a "purging" election to recognize gain as discussed in the preceding sentence, then such U.S. Holder shall be subject to the QEF Election rules and shall continue to be subject to tax under the rules of Section 1291 discussed above with respect to our common shares. If a U.S. Holder owns PFIC stock indirectly through another PFIC, separate QEF Elections must be made for the PFIC in which the U.S. Holder is a direct shareholder and the Subsidiary PFIC for the QEF rules to apply to both PFICs.

A QEF Election will apply to the tax year for which such QEF Election is timely made and to all subsequent tax years, unless such QEF Election is invalidated or terminated or the IRS consents to revocation of such QEF Election. If a U.S. Holder makes a QEF Election and, in a subsequent tax year, we cease to be a PFIC, the QEF Election will remain in effect (although it will not be applicable) during those tax years in which we are not a PFIC. Accordingly, if we become a PFIC in another subsequent tax year, the QEF Election will be effective and the U.S. Holder will be subject to the QEF rules described above during any subsequent tax year in which we qualify as a PFIC.

We: (a) will make available to U.S. Holders, upon their written request, information as to our status as a PFIC, and (b) for each taxable year in which we are a PFIC, provide to a U.S. Holder, upon written request, such information and documentation that a U.S. Holder making a QEF Election with respect to the Company is reasonably required to obtain for U.S. federal income tax purposes. We may elect to provide such information on our website. However, U.S. Holders should be aware that we cannot assure that we will provide any such information relating to any Subsidiary PFIC. Because we may own shares in one or more Subsidiary PFICs at any time, U.S. Holders will continue to be subject to the rules discussed above with respect to the taxation of gains and excess distributions with respect to any Subsidiary PFIC for which the U.S. Holders do not obtain the required information. Each U.S. Holder should consult its own tax advisors regarding the requirements for, and procedure for making, a QEF Election with respect to the Company and any Subsidiary PFIC.

A U.S. Holder makes a QEF Election by attaching a completed IRS Form 8621, including a PFIC Annual Information Statement, to a timely filed United States federal income tax return. However, if we do not provide the required information with regard to the Company or any of our Subsidiary PFICs, U.S. Holders may not be able to make a QEF Election for such entity and, unless they make the Mark-to-Market Election discussed in the next section, will continue to be subject to the rules of Section 1291 of the Code discussed above that apply to Non-Electing U.S. Holders with respect to the taxation of gains and excess distributions.

Mark-to-Market Election

A U.S. Holder may make a Mark-to-Market Election only if our common shares are marketable stock. Our common shares generally will be "marketable stock" if our common shares are regularly traded on (a) a national securities exchange that is registered with the Securities and Exchange Commission, (b) the national market system established pursuant to section 11A of the Exchange Act, or (c) a foreign securities exchange that is regulated or supervised by a governmental authority of the country in which the market is located, provided that (i) such foreign exchange has trading volume, listing, financial disclosure, and surveillance requirements, and meets other requirements and the laws of the country in which such foreign exchange is located, together with the rules of such foreign exchange, ensure that such requirements are actually enforced and (ii) the rules of such foreign exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. We expect that our common shares will meet the definition of "marketable stock," although there can be no assurance of this, especially as regards the required trading frequency.

If a U.S. Holder that makes a Mark-to-Market Election for any taxable year with respect to our common shares, it generally will not be subject to the rules of Section 1291 of the Code discussed above with respect to such common shares for such taxable year. However, if a U.S. Holder does not make a Mark-to-Market Election beginning in the first tax year of such U.S. Holder's holding period for which we are a PFIC and such U.S. Holder has not made a timely QEF Election, the rules of Section 1291 of the Code discussed above will apply to dispositions of, and certain distributions on, our common shares.

A U.S. Holder that makes a Mark-to-Market Election will include in ordinary income, for each tax year in which we are a PFIC, an amount equal to the excess, if any, of (a) the fair market value of our common shares, as of the close of such tax year over (b) such U.S. Holder's adjusted tax basis in such common shares. A U.S. Holder that makes a Mark-to-Market Election will be allowed a deduction in an amount equal to the excess, if any, of (a) such U.S. Holder's adjusted tax basis in our common shares, over (b) the fair market value of such common shares (but only to the extent of the net amount of previously included income as a result of the Mark-to-Market Election for prior tax years).

A U.S. Holder that makes a Mark-to-Market Election generally also will adjust its tax basis in our common shares to reflect the amount included in gross income or allowed as a deduction because of such Mark-to-Market Election. Upon a sale or other taxable disposition of our common shares, a U.S. Holder that makes a Mark-to-Market Election will recognize ordinary income or ordinary loss. Any such ordinary loss, however, is limited to exceed the excess, if any, of (a) the amount included in ordinary income because of such Mark-to-Market Election for prior tax years over (b) the amount allowed as a deduction because of such Mark-to-Market Election for prior tax years. Losses that exceed this limitation are subject to the rules generally applicable to losses provided in the Code and Treasury Regulations, with the result that they will be capital losses for most U.S. Holders.

A U.S. Holder makes a Mark-to-Market Election by attaching a completed IRS Form 8621 to a timely filed United States federal income tax return. A Mark-to-Market Election applies to the tax year in which such Mark-to-Market Election is made and to each subsequent tax year, unless our common shares cease to be "marketable stock" or the IRS consents to revocation of such election. Each U.S. Holder should consult its own tax advisors regarding the requirements for, and procedure for making, a Mark-to-Market Election.

Although a U.S. Holder may be eligible to make a Mark-to-Market Election with respect to our common shares, no such election may be made with respect to the stock of any Subsidiary PFIC that a U.S. Holder is treated as owning, because such stock is not marketable. Hence, the Mark-to-Market Election will not be effective to avoid the application of the default rules of Section 1291 of the Code described above with respect to deemed dispositions of Subsidiary PFIC stock or excess distributions from a Subsidiary PFIC to its shareholder.

Other PRIC and Related Rules

Under Section 1291(f) of the Code, the IRS has issued proposed Treasury Regulations that, subject to certain exceptions, would cause a U.S. Holder that had not made a timely QEF Election or Mark-to-Market Election to recognize gain (but not loss) upon certain transfers of our common shares that would otherwise be tax-deferred (e.g., gifts and exchanges pursuant to corporate reorganizations). However, the specific U.S. federal income tax consequences to a U.S. Holder may vary based on the manner in which our common shares are transferred.

Certain additional adverse rules may apply with respect to a U.S. Holder if we are a PFIC, regardless of whether such U.S. Holder makes a QEF Election. For example, under Section 1298(b)(6) of the Code, a U.S. Holder that uses our common shares as security for a loan will, except as may be provided in Treasury Regulations, be treated as having made a taxable disposition of such common shares.

Special rules also apply to the amount of foreign tax credit that a U.S. Holder may claim on a distribution from a PFIC. Subject to such special rules, foreign taxes paid with respect to any distribution in respect of stock in a PFIC are generally eligible for the foreign tax credit. The rules relating to distributions by a PFIC and their eligibility for the foreign tax credit are complicated, and each U.S. Holder should consult with its own tax advisors regarding the availability of the foreign tax credit with respect to distributions by a PFIC.

If U.S. Holders of our common shares or U.S. Holders that are treated as constructively owning our common shares, each owning 10 percent or more of our equity by vote ("10-percent Shareholders") own in total more than 50 percent of such equity by either vote or value, we will be treated as a controlled foreign corporation ("CFC"). For our taxable year ending December 31, 2019 and subsequent years, and for taxable years of U.S. Holders ending with or within such years, the test for a 10-percent Shareholder will be whether the holder owns 10 percent of our equity by vote or value (i.e., not only by vote). If we are a CFC, a 10-percent Shareholder would be treated, subject to certain exceptions, as receiving a deemed dividend at the end of each taxable year of the Company in an amount equal to its pro rata share of the Company's "subpart F income." Among other items, and subject to certain exceptions, "subpart F income" includes dividends, interest, certain rents and royalties, certain gains from the sale of stock and securities, and certain gains from commodities transactions. Thus, it is likely that, if we were treated as a CFC, some of our income would be subpart F income. If, for any period, we were treated as a CFC and a U.S. Holder were treated as a 10-percent Shareholder therein, we would not be treated as a PFIC with respect to such U.S. Holder for such period.

The PFIC and CFC rules are complex, and each U.S. Holder should consult with its own tax advisors regarding the PFIC and CFC rules and how they may affect the U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares.

Additional Considerations

Additional Tax on Passive Income

Certain U.S. Holders that are individuals, estates or trusts (other than trusts that are exempt from tax) will be subject to a 3.8% tax on all or a portion of their "net investment income," which includes dividends on our common shares and net gains from the disposition of our common shares. Further, excess distributions treated as dividends, gains treated as excess distributions under the PFIC rules discussed above, and mark-to-market inclusions and deductions are all included in the calculation of net investment income.

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 our common shares that will be subject to the additional tax on net investment income, a U.S. Holder who has made a QEF Election will be required to recalculate its basis in our common shares excluding QEF basis adjustments.

Alternatively, a U.S. Holder may make an election which will be effective with respect to all interests in a PFIC for which a QEF 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 QEF income inclusions and on gains calculated after giving effect to related tax basis adjustments. 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 our 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 our 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). A U.S. Holder will have a 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 above, a U.S. Holder that pays (whether directly or through withholding) Canadian income tax with respect to dividends paid on our 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. 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 on our common shares should be treated as foreign source for this purpose, and gains recognized on the sale of our common shares 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 our 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.

Backup Withholding and Information Reporting

A U.S. Holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to certain reporting obligations with respect to our common shares if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the IRS. Significant penalties can apply if a U.S. Holder is required to make this disclosure and fail to do so. In addition, a U.S. Holder should consider the possible obligation to file online a FinCEN Form 114—Foreign Bank and Financial Accounts Report, as a result of holding our common shares in certain accounts. Holders are urged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of our common shares.

Payments made within the U.S., or by a U.S. payor or U.S. middleman, of dividends on, and proceeds arising from the sale or other taxable disposition of, our common shares will generally be subject to information reporting and backup withholding tax, at the rate of 28%, if a U.S. Holder (a) fails to furnish such U.S. Holder's correct U.S. taxpayer identification number (generally on Form W-9), (b) furnishes an incorrect U.S. taxpayer identification number, (c) is notified by the IRS that such U.S. Holder has previously failed to report properly items subject to backup withholding tax, or (d) fails to certify, under penalty of perjury, that such U.S. Holder has furnished its correct U.S. taxpayer identification number and that the IRS has not notified such U.S. Holder that it is subject to backup withholding tax. However, certain exempt persons generally are excluded from these information reporting and backup withholding rules. Backup withholding is not an additional tax. Any amounts withheld under the U.S. backup withholding tax rules will be allowed as a credit against a U.S. Holder's U.S. federal income tax liability, if any, or will be refunded, if such U.S. Holder furnishes required information to the IRS 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. Each U.S. Holder should consult its own tax advisors regarding the information reporting and backup withholding rules.

THE ABOVE SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO U.S. HOLDERS WITH RESPECT TO THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF OUR COMMON SHARES. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE TAX CONSIDERATIONS APPLICABLE TO THEM IN THEIR OWN PARTICULAR CIRCUMSTANCES.

Material Canadian Federal Income Tax Considerations

Non-Residents of Canada

The following portion of the summary is generally applicable to a U.S. Holder who, for the purposes of the Tax Act, is not resident in Canada, holds our common shares as capital property and does not hold our common shares in connection with any business carried on in Canada. 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 our common shares, 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 constitute "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. Our 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 (i) directly or indirectly holds 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 Canada-U.S. Tax Convention, 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 Canada-U.S. Tax Convention, however a member of such entity will be considered to have received the dividend directly and to benefit from the reduced rates under the Canada-U.S. Tax Convention, 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 Canada-U.S. Tax Convention. As discussed above under "Dividend Policy," we have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends in the foreseeable future.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

CAUTIONARY STATEMENT

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

Overview

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

- PEDMARK™ (sodium thiosulfate (STS) anhydrous injection) –has announced results of two Phase 3 clinical trials for the prevention of cisplatin induced hearing loss, or ototoxicity in children including the pivotal Phase 3 study SIOPEL 6 , "A Multicentre Open Label Randomised Phase 3 Trial of the Efficacy of Sodium Thiosulfate in Reducing Ototoxicity in Patients Receiving Cisplatin Chemotherapy for Standard Risk Hepatoblastoma," and the proof of concept Phase 3 study "A Randomized Phase 3 Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children".

We continue to focus our resources on the development of PEDMARK™.

We have licensed from OHSU intellectual property rights for the use of PEDMARK™ as a chemoprotectant and are developing PEDMARK™ as a protectant against the hearing loss often caused by platinum-based anti-cancer agents in children. Preclinical and clinical studies conducted by OHSU and others have indicated that PEDMARK™ can effectively reduce the incidence of hearing loss caused by platinum-based anti-cancer agents. We have received Orphan Drug Designation in the United States for the use of PEDMARK™ in the prevention of platinum-induced ototoxicity in pediatric patients.

Hearing loss among children receiving platinum-based chemotherapy is frequent, permanent and often severely disabling. The incidence of hearing loss in these children depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. In addition, adults undergoing chemotherapy for several common malignancies, including ovarian cancer, testicular cancer, and particularly head and neck cancer and brain cancer, often receive intensive platinum-based therapy and may experience severe, irreversible hearing loss, particularly in the high frequencies.

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

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

In July 2018, the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) accepted our pediatric investigation plan (PIP) for Sodium Thiosulfate for Infusion for the condition of the prevention of platinum-induced ototoxic hearing loss. An accepted PIP is a prerequisite for filing a full Marketing Authorization Application (MAA) for a new medicinal product in Europe. The indication targeted by the Company's PIP is for the prevention of platinum-induced ototoxic hearing loss for standard risk hepatoblastoma (SR-HB). Additional tumor types within the proposed MAA indication will be subject to the Committee for Medicinal Products for Human Use (CHMP) assessment at the time of the MAA. No deferred clinical studies were required in the positive opinion given by PDCO. The Company was also advised that Sodium Thiosulfate for Infusion is eligible for submission of an application for a Pediatric Use Marketing Authorization (PUMA). Therefore, this PIP decision allows Fennec to proceed with the submission of a PUMA in the European Union (EU) with incentives of automatic access to the centralized procedure and up to 10 years of data and market protection. The PUMA is a dedicated MA for new products of medicines previously authorized and no longer under data or marketing protection, covering the indication and appropriate formulation for medicines developed exclusively for use in the pediatric population. In February 2020, Fennec announced that it has submitted a MAA for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. The Company is targeting potential commercial launch of Sodium Thiosulfate for Infusion, if approved, in the first half of 2021.

We initiated our rolling FDA New Drug Application ("NDA") for PEDMARKTM (tradename for Sodium Thiosulfate for Infusion in the US) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors in December 2018. Fennec announced that it has completed its rolling submission of the NDA in February 2020. The Company is targeting a potential commercial launch of PEDMARKTM, if approved, in the second half of 2020. In March 2018, PEDMARKTM received Breakthrough Therapy and Fast Track designations from the FDA. Further, PEDMARKTM has received Orphan Drug Designation in the US in this setting.

We have not received and do not expect to have significant revenues from our product candidate until we are either able to sell our product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide us with up-front payments, licensing fees, milestone payments, royalties or other revenue. We generated a net loss of $12.8 million for the year ended December 31, 2019. We generated a net loss of approximately $9.9 million for the year ended December 31, 2018 and had a non-cash gain on the change in derivative liability of $0.2 million. As of December 31, 2019, our accumulated deficit was approximately $144.0 million.

Our projections of our capital requirements are subject to substantial uncertainty. More capital than we anticipated may be required thereafter. To finance our continuing operations, we may need to raise substantial additional funds through either the sale of additional equity, the issuance of debt, the establishment of collaborations that provide us with funding, the out-license or sale of certain aspects of our intellectual property portfolio or from other sources. We may not be able to raise the necessary capital or such funding may not be available on financially acceptable terms if at all. If we cannot obtain adequate funding in the future, we might be required to further delay, scale back or eliminate certain research and development studies, consider business combinations or even shut down some, or all, of our operations.

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

On February 1, 2019, Fennec entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, an Arizona corporation, pursuant to which the Bank agreed to loan $12.5 million to the Company, to be made available if we receive NDA approval of PEDMARK^{TM} by no later than September 30, 2020. The proceeds from the loan will be used for working capital purposes and to fund general business requirements in accordance with the terms of the Loan and Security Agreement. Interest under the Term Loans shall bear interest, on the outstanding daily balance thereof, at a floating per annum rate equal to the Effective Interest Rate (as defined in the Loan and Security Agreement) which is equal to the sum of the Prime Rate published in the Wall Street Journal (currently 4.75%) plus one percent (1.00%). The debt facility is to have interest-only monthly payments due for the first eighteen months from the funding date and then monthly principal and interest payments are due through the remainder of the term which has a maturity date of October 1, 2023. In connection with the facility, Fennec granted Bridge Bank a warrant to purchase up to 39,130 common shares at an exercise price of $6.80 per common share, for a term of ten years from the date of issuance, subject to early termination under certain conditions.

Results of Operations

Fiscal 2019 versus Fiscal 2018

In thousands of U.S. Dollars	Fiscal Year Ended December 31, 2019	%	Fiscal Year Ended December 31, 2018	%	Increase (Decrease)
Revenue	$ -		$ -		$ -
Operating expenses:					
Research and development	5,607	43%	5,008	48%	599
General and administration	7,402	57%	5,401	52%	2,001
Total operating expense	13,009	100%	10,409	100%	2,600
Derivative income/(loss)	-		167		(167)
Amortization expense	(64)		-		(64)
Other loss	(17)		6		(23)
Interest income and other, net	315		348		(33)
Net income (loss)	**$ (12,775)**		**$ (9,888)**		**$ (2,887)**

- Research and development expense increased by $0.6 million in fiscal 2019 as compared to fiscal 2018, primarily due to drug manufacturing activities related to the preparation for registration batches and additional regulatory activities in preparation for the submission of our new drug application to each of the FDA and EMA.
- The $2.0 million increase in general and administrative expenses is attributed to a small rise in compensation to officers, directors and key contract employees in fiscal 2019 as compared to fiscal 2018. Shareholders passed a motion to increase the exercise period of all outstanding option contracts to a total of ten years in 2019. This added $1.3 million in G&A in non-cash compensation over the prior year. Sales and marketing expenses increased by $0.4 million over the prior year as we began to focus efforts to commercialize PEDMARK™. We incurred approximately $0.25 million in executive search services as we continue to build a commercial team.
- All of our derivative instruments were exercised or expired during fiscal 2018.
- Amortization expense relates to the Bridge Bank loan facility as the loan origination fees were capitalized in fiscal 2019.
- Interest income decreased in fiscal 2019 as compared to 2018, due to a lower average balance in savings and money market accounts for the comparable periods.

Quarterly Information

The following table presents selected consolidated financial data for each of the last eight quarters through December 31, 2019, as prepared under U.S. GAAP (dollars in thousands, except per share information).

Period	Net (Loss)/Income for the Period	Basic Net (Loss)/Income per Common Share	Diluted Net (Loss)/Income per Common Share
March 31, 2018	(1,568)	(0.09)	(0.09)
June 30, 2018	(2,587)	(0.14)	(0.14)
September 30, 2018	(2,749)	(0.14)	(0.14)
December 31, 2018	(2,984)	(0.15)	(0.15)
March 31, 2019	(2,626)	(0.13)	(0.13)
June 30, 2019	(4,730)	(0.24)	(0.24)
September 30, 2019	(1,809)	(0.09)	(0.09)
December 31, 2019	(3,610)	(0.18)	(0.18)

Quarter ended December 31, 2019 versus 2018

In thousands of U.S. Dollars	Quarter Ended December 31, 2019	%	Quarter Ended December 31, 2018	%	Increase (Decrease)
Revenue	$ -		$ -		$ -
Operating expenses:					
Research and development	1,172	32%	1,723	55%	(551)
General and administration	2,481	68%	1,382	45%	1,099
Total operating expense	3,653	100%	3,105	100%	548
Interest income	69		115		(46)
Amortization expense	(18)		-		(18)
Other(loss)/income, net	(8)		6		(14)
Net (loss)	**$ (3,610)**		**$ (2,984)**		**$ (626)**

We reported a net loss from operations of $3.6 million for the three months ended December 31, 2019, compared to a net loss from operations of $3.0 million for the same period in 2018. Research and development expenses totaled $1.1 million for the three months ended December 31, 2019, as compared to a $1.7 million in the same period in 2018 as largely most cost associated with the production of registration batches was incurred in the first three quarters of 2019. General and administrative expenses increased by $1.1 million in the three months ended December 31, 2019, as compared to the same period in 2018. The increase arises from our commercialization activities for PEDMARK™ as we execute on our plan to be ready to bring product to market co-incidentally with FDA approval, expected to occur later in 2020. There were also increases in compensation expenses in fiscal 2019 as we hired a Chief Commercial Officer in September 2019.

Selected Asset and Liability Data (thousands):	As at December 31, 2019	As at December 31, 2018
Cash and equivalents	$ 13,650	$ 22,781
Other current assets	234	169
Current liabilities	2,271	1,637
Working capital [current assets – current liabilities]	11,613	21,313

Selected Asset and Liability Data (thousands):	As at December 31, 2019	As at December 31, 2018
Selected Equity:		
Common stock and additional paid in capital	$ 154,663	$ 151,326
Accumulated deficit	(144,031)	(131,256)
Shareholders' equity	11,875	21,313

Liquidity and Capital Resources

- There was a $9.1 million decrease in cash and cash equivalents between December 31, 2019 and December 31, 2018. During the period ended December 31, 2019, cash for operations was used mainly in regulatory and manufacturing activities and our general and administrative expenses.
- The increase in other current assets between December 31, 2019 and December 31, 2018 primarily relates to an increase in the prepaid amount for Director and Officer insurance premiums and prepaid conference expenses.
- Current liabilities at December 31, 2019 increased from December 31, 2018 primarily due to an increase in accounts payable associated with our commercialization and manufacturing activities for the production of PEDMARK™ and related regulatory expenses at year-end 2019.
- Working capital decreased between December 31, 2019 and December 31, 2018 by $9.7 million. The decrease was a result of cash used in operations offset by $0.3 million interest income and the capitalization of $0.3 million loan origination expenses. Cash outflows related to the regulatory and commercial development of PEDMARK™ and general and administrative expenses. We expect increased cash outflows as we prepare regulatory submission and commercial preparation to launch PEDMARK™.

Selected Cash Flow Data (dollars and shares in thousands)	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash used in operating activities	$ (9,060)	$ (7,826)
Net cash provided from investing activities	-	-
Net cash provided from financing activities	(71)	2,347
Net cash flow	$ (9,131)	$ (5,479)

The net cash flow used in operating activities for the year ended December 31, 2019 was approximately $9.1 million as compared to $7.8 million in 2018. This increase relates to the regulatory and commercial development of PEDMARK™.

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 $13.7 million as of December 31, 2019. We currently anticipate that our available capital resources, including our existing cash and cash equivalents and 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. As of the date of this filing, we have secured the availability of an additional $12.5 million of debt financing which will be funded if we receive FDA approval of PEDMARK™ by no later than September 30, 2020.

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, 2019, we had approximately $0.4 million in our cash accounts and $13.3 million in savings and money market accounts. We have never experienced any loss or write down of our money market investments since our inception.

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

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

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

None.

Critical Accounting Policies and Estimates

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

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. The following description of critical accounting policies, judgments and estimates should be read in conjunction with our December 31, 2019 consolidated financial statements.

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, 2019 and 2018, we used the following weighted average assumptions:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Expected dividend	0%	0%
Risk-free interest rate	1.63 – 2.70%	2.53 – 3.00%
Expected volatility	125 – 179%	132– 151%
Expected life	4.3 – 10.0 years	4.5 – 7.0 years

Common shares and warrants

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

Derivative Instruments

The Company applies ASC Topic 815-40, "Derivatives and Hedging" (ASC 815-40). One of the conclusions reached under ASC 815-40 was that an equity-linked financial instrument would not be considered indexed to the entity's own stock if the strike price is denominated in a currency other than the issuer's functional currency. The conclusion reached under ASC 815-40 clarified the accounting treatment for these and certain other financial instruments. ASC 815-40 specifies that a contract will not be treated as a derivative if it meets the following conditions: (a) indexed to our own stock; and (b) classified in stockholders' equity in our statement of financial position. Our options issued to consultants and denominated in Canadian dollars were not considered to be indexed to our own stock because the exercise price is denominated in Canadian dollars and our functional currency is United States dollars. Therefore, these options were treated as derivative financial instruments and recorded at their fair value as a liability. All other outstanding convertible instruments are considered to be indexed to our stock, because their exercise price is denominated in the same currency as our functional currency, and are included in stockholders' equity.

During the year ended December 31, 2018, there were exercises of options to purchase 19 shares of our common shares, which were classified as derivative instruments. This resulted in gross proceeds of $26 and a non-cash gain on the extinguishment of the remaining derivative liability of $167. The fair value of these options was estimated using the Black-Scholes option-pricing model and is summarized below.

	Gain/(Loss) on Derivative Instrument December 31,	
Derivative Options	**2019**	**2018**
Options (various expiration dates)	-	167
Total	**-**	**167**

Outstanding Share Information

Our outstanding comparative share data at December 31, 2019 and December 31, 2018 is as follows (in thousands):

Outstanding Share Type	**December 31, 2019**	**December 31, 2018**
Common shares	19,896	19,896
Warrants to purchase common shares	39	-
Options to purchase common shares	3,088	2,498
Total	23,023	22,394

Newly Adopted and Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 removes certain disclosures, modifies certain disclosures and adds additional disclosures. The ASU is effective for us on January 1, 2020, and interim periods within that fiscal year. Early adoption is permitted. Certain disclosures in ASU 2018-13 would need to be applied on a retrospective basis and others on a prospective basis. The Company concluded after evaluation that ASU 2018-13 will have no significant effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new guidance requires the recognition of lease liabilities, representing future minimum lease payments, on a discounted basis, and corresponding right-of-use assets on a balance sheet for most leases, along with requirements for enhanced disclosures to give financial statement users the ability to assess the amount, timing and uncertainty of cash flows arising from leasing arrangements. In July 2018, the FASB issued ASU 2018-10 and 2018-11 which permit application of the new guidance at the beginning of the year of adoption, recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, in addition to the method of applying the new guidance retrospectively to each prior reporting period presented. The ASU was effective for us on January 1, 2019. We concluded the impact of this guidance is negligible on our consolidated financial statements, given we have no material leases.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Money Market Investments

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

At December 31, 2019, we had $13.3 million in money market investments and savings accounts as compared to $22.0 million at December 31, 2018; 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, 2019 and 2018.

Our investment policy is to manage investments to achieve, in the order of importance, the financial objectives of preservation of principal, liquidity and return on investment. Our risk associated with fluctuating interest rates on our investments is minimal and not significant to the results of operations. We currently do not use interest rate derivative instruments to manage exposure to interest rate changes. As our main purpose is research and development, we have chosen to avoid investments of a trade or speculative nature.

Foreign Currency Exposure

We are subject to foreign currency risks as we purchase goods and services which are denominated in Canadian dollars. To date, we have not employed the use of derivative instruments; however, we do hold Canadian dollars which we use to pay vendors in Canada and other corporate obligations. At December 31, 2019, we held approximately thirty thousand Canadian dollars.

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 on Form 10-K. A list of the financial statements filed herewith is found at “Index to Financial Statements” on Page F-1.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is (i) recorded, processed, summarized, and reported, within the time periods specified in the Commission’s rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

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

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of Consolidated Financial Statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our Consolidated Financial Statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making its assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in its 2013 *Internal Control — Integrated Framework*. Based on its assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Control over Financial Reporting

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

Inherent Limitation on the Effectiveness of Internal Controls

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

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

Name and Province/State and Country of Residence, Position	Current Principal Occupation and Principal Occupation For Previous Five Years	Director Since	Age
Rostislav Raykov, New Jersey, USA Chief Executive Officer, Director	CEO of Fennec Pharmaceuticals Inc.; Co-Founder and Manager, DCML LLC; previously Portfolio Manager at Alchem Partners; previously Portfolio Manager at John Levin & Company	July 2009	44
Robert Andrade, Texas, USA Chief Financial Officer	CFO of Fennec Pharmaceuticals; previously senior analyst at Magnetar Capital; previously Portfolio Manager at Millennium Partners	September 2009-August 2013; November 2015-Present	44
Shubh Goel, New Jersey, USA Chief Commercial Officer	CCO of Fennec Pharmaceuticals Inc.; previously VP of Commercial Strategy and Operations at Odonate Therapeutics, Inc.; previously Executive Director, Global Early Commercialization at Celgene Corporation	September 2019	46
Chris A. Rallis, North Carolina, USA Director(1)(2)	Executive in-residence at Pappas Capital; previously CEO of ImmunoBiosciences	August 2011	65
Marco Brughera, Milano, Italy Director(2)(3)	CEO of Leadiant Biosciences SpA; previously Global Head Rare Disease and R&D at Sigma-tau; VP Preclinical Development at Nerviano Medical Sciences.	August, 2016	63
Adrian J. Haigh, Dublin, Ireland Director(1)(3)	Senior Vice President and General Manager of EMEA Region at PTC Therapeutics; previously Chief Operating Officer at Gentium GmbH; previously Regional VP Commercial Operations at Biogen Idec	April 2014	59
Khalid Islam, Zug, Switzerland Chairman of Board, Director(1)	Founder/co-founder of Sirius Healthcare Partners GMbH; previously Chairman and CEO of Gentium S.p.A.; previously CEO of Arpida AG	April 2014	63
Jodi Cook, Cambridge, Massachusetts, Director(2)(3)	SVP, Head of Gene Therapy Strategy PTC Therapeutics, Inc.	September 2019	52

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

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

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

Shubh Goel
Ms. Goel has been employed by us since September 2019. Pursuant to an employment agreement dated September 9, 2019, Ms. Goel is employed as Fennec's Chief Commercial Officer and: (a) received an initial annual salary in the amount of $360,000, subject to annual adjustment by our Board of Directors, and (b) may receive annual bonus of up to 40% of her base salary per twelve month period, at the discretion of the CEO and the Board of Directors. If Ms. Goel's employment is terminated by us for any reason other than "for cause", we are obligated to pay Ms. Goel (i) severance in the amount of three months of employees base salary or if such termination occurs either (a) after the second anniversary of her employment or (b) as a result of a Change of Control a severance in the amount of six months, (ii) prorate share of any target bonus earned by Ms. Goel and, (iii) accelerated vesting of stock options. The initial term of the agreement was for one year and the agreement automatically extends for additional one-year periods unless terminated by either party in accordance with the agreement.

Chris A. Rallis
Mr. Rallis has served as a director of Fennec since August 2011. Mr. Rallis has been an executive-in-residence at Pappas Capital, a life science venture capital firm since January 2008. Previously, Mr. Rallis was the President and Chief Executive Officer of ImmunoBiosciences, Inc. ("IBI"), a vaccine technology company formerly located in Raleigh, North Carolina from April 2006 through June 2007. Prior to joining IBI, Mr. Rallis served as an executive in residence (part-time) for Pappas Ventures, and as a consultant for Duke University and Panacos Pharmaceuticals, Inc. Mr. Rallis is the former President and Chief Operating Officer ("COO") and director of Triangle Pharmaceuticals, Inc., which was acquired by Gilead Sciences in January 2003 for approximately $465 million. Prior to assuming the role of President and COO in March 2000, he was Executive Vice President, Business Development and General Counsel. While at Triangle, Mr. Rallis participated in 11 equity financings generating gross proceeds of approximately $500 million. He was also primarily responsible for all business development activities which included a worldwide alliance with Abbott Laboratories and the in-licensing of ten compounds. Before joining Triangle in 1995, Mr. Rallis served in various business development and legal management roles with Burroughs Wellcome Co. over a 13-year period, including Vice President of Strategic Planning and Business Development. Mr. Rallis also served on the boards of Aeolus Pharmaceuticals, a biopharmaceutical company located in Mission Viejo, California (no longer active) and Tenax Therapeutics, Inc., a biopharmaceutical company located in Morrisville, North Carolina. Mr. Rallis received his A.B. degree in economics from Harvard College and a J.D. from Duke University. As a result of these and other professional experiences, Mr. Rallis possesses particular healthcare industry knowledge and experience which strengthens the Board's collective qualifications, skills, and experience.

Marco Brughera
Since January 2011, Dr. Brughera has been CEO of Lediant Biosciences SpA and has held several positions for the Sigma-Tau Group, including CEO and Global Head of Sigma Tau Rare Disease, President of Sigma-Tau Research and President of Sigma-Tau Pharmaceuticals. He drove the commercial revival of a lead oncology product line resulting in its successful sale for a total of around $900M. He also successfully out-licensed the Defibrotide US rights to Jazz Pharmaceuticals. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Sciences (NMS), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, an independent contract research organization with the NMS Group. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of research and development with Pharmacia and Pfizer. Prior to 1999, he held various positions at Pharmacia & Upjohn and Farmitalia Carlo Erba SpA, an Italian pharmaceutical company. He currently serves on the Board of Solgenix and Lee's Pharmaceutical and until early 2014 was a member of the Board of Gentium SpA. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist Mr. Brughera has wide-spread experience and knowledge of pharmaceutical drug development in international companies. His knowledge in particular, of clinical drug development in Europe, deepens the Board's collective qualifications, skills and experience.

Adrian J. Haigh
Mr. Adrian Haigh has been Senior Vice President and General Manager of EMEA Region and Asia Pacific at PTC Therapeutics, Inc. since September 2014. Previously Mr. Haigh served as Senior Vice President, Commercial Operations and Chief Operating Officer of Gentium GmbH since March 2011. Prior to joining Gentium, Mr. Haigh served as Regional Vice President, Commercial Operations at Biogen Idec where he managed several affiliates and also the global distributor business and prior to that was the General Manager of Amgen Nordis and Portugal. He served as the Executive Vice President of Global Marketing and Corporate Planning at EUSA Pharma and joined EUSA from Amgen where he led the international oncology franchise. Mr. Haigh previously has held senior commercial and marketing positions at SmithKline Beecham, Schering Plough, Organon and Novo Nordisk. He has been a Director of Fennec Pharmaceuticals Inc. since April 28, 2014 and a Director at Arch Biopartners Inc. since August 21, 2014. He received a Bachelor of Arts with Honors in Economic History from Huddersfield Polytechnic, West Yorkshire, England and a Diploma in Marketing from the Institute of Marketing. As a result of these and other professional experiences, Mr. Haigh has extensive international oncology development expertise which strengthens the Board's collective qualifications, skills and experience.

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

Jodi Cook
Dr. Cook currently serves as Head of Gene Therapy Strategy at PTC Therapeutics, Inc., a global biopharmaceutical company focused on the development and commercialization of clinically differentiated medicines that provide benefits to patients with rare disorders. Prior to joining PTC Therapeutics, she was one of the founding members and Chief Operating Officer of Agilis Biotherapeutics, a clinical-stage company focused on gene therapies for patients with rare diseases. Importantly, her career spans a wide range of experience relevant to Fennec's business interests including Assistant Professor of Audiology and Director of the Hearing Aid Program at Mayo Clinic, and executive positions in a number of successful biotech start-ups within the hearing industry. While at Agilis, she led the sale of the company to PTC Therapeutics in a deal that has represented significant value to all parties. Her extensive scientific, clinical and executive business experience deepens the Board's collective qualifications, skills and experience.

Audit Committee

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

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

Code of Ethics

In February 2004, our Board adopted a Mandate of the Board of Directors, Corporate Governance Guidelines and a Code of Business Conduct and Ethics (the "Conduct and Ethics Code") applicable to all of our officers, directors and employees. We are committed to adhering to applicable legal requirements and maintaining the highest standards of conduct and integrity. The Conduct and Ethics Code sets out the legal and ethical standards of conduct for our personnel and addresses topics such as: reporting obligations and procedures; honest and ethical conduct and conflicts of interest; compliance with applicable laws and Company policies and procedures; confidentiality of corporate information; use of corporate assets and opportunities; public disclosure and books and records; and non-retaliation. The Conduct and Ethics Code was updated in June of 2019 and is available on our website at www.fennecpharma.com.

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

Section 16(a) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Exchange Act, our directors and executive officers and any person who beneficially owns more than 10% of our outstanding common shares ("reporting persons") are required to report their initial beneficial ownership of our common shares and any subsequent changes in that ownership to the SEC and Nasdaq. Reporting persons are required by SEC regulations to furnish to us copies of all reports they file in accordance with Section 16(a). Based solely upon our review of the copies of such reports received by us, or written representations from certain reporting persons that no other reports were required, we believe that during the fiscal year ended December 31, 2019, all Section 16(a) filing requirements applicable to our reporting persons were met.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets out certain information respecting the compensation paid to our Chief Executive Officer and our Chief Financial Officer ("Named Executive Officers") for the fiscal years ended December 31, 2019 and December 31, 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	Total ($)
Rostislav Raykov, CEO	2019	488,692	157,500	830,944	1,476,536
	2018	350,000	160,000	562,261	1,072,261
Robert Andrade, CFO	2019	325,211	100,000	438,555	863,766
	2018	250,000	110,000	309,099	669,099
Shubh Goel, CCO[2]	2019	98,000	115,000	816,538	1,029,538
	2018	-	-	-	-

(1) Represents the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Dollar value amounts are based on individual grants to each of Mr. Raykov and Mr. Andrade of 150,000 and 100,000 and 80,000 and 50,000 options, respectively, on April 4, 2019 and February 6, 2018, at an exercise price of $4.38 and $8.38 per common share, respectively. The grant to Ms. Goel was dated September 9, 2019 at an exercise price of $4.74. All option grants expire 10 years after grant date. One-third of these options shall vest and may be exercised one year after the grant date (the "Vesting Commencement Date"). The remaining two-thirds of the options shall vest monthly at a rate of 1/36th of the remaining grant and shall be exercisable as of the last day of each following month after the Vesting Commencement Date. As of the third anniversary of the grant date, all of the options shall be vested.

(2) Ms. Goel was hired as our Chief Commercial Officer in September 2019

Rostislav Raykov
Mr. Raykov has been employed by us since July 2009. Pursuant to an employment agreement dated May 3, 2010 between Mr. Raykov and Fennec, Mr. Raykov is employed as our Chief Executive Officer and: (a) received an initial annual salary in the amount of $140,000, subject to annual adjustment by our Board of Directors, (b) upon approval by shareholders of our amended stock option plan was granted options to purchase up to 5.0% of our common shares estimated by us to be outstanding upon completion of the 2010 Rights Offering, and (c) may receive annual bonuses at the sole discretion of the Board. If Mr. Raykov's employment terminates due to a change of control of Fennec, Mr. Raykov's remaining unvested options shall immediately vest and be fully exercisable. If Mr. Raykov is dismissed from employment by us for any reason other than "for cause," we are obligated to pay Mr. Raykov severance compensation equal to twelve months of salary. The initial term of the agreement was for one year and the agreement automatically extends for additional one-year periods unless terminated by either party in accordance with the agreement. Effective April 1, 2019, Mr. Raykov's salary was increased to $400,000 per year.

Robert Andrade
Mr. Andrade has been employed by us since November 2015. Mr. Andrade is employed as Fennec's Chief Financial Officer. Pursuant to an employment agreement dated November 13, 2015, Mr. Andrade (a) receives an initial annual salary in the amount of $165,000, and (b) may receive annual bonuses at the sole discretion of the Board. If Mr. Andrade's employment terminates due to a change of control of the Fennec, Mr. Andrade's remaining unvested options shall immediately vest and be fully exercisable. If Mr. Andrade is dismissed from employment by us for any reason other than "for cause," we are obligated to pay Mr. Andrade severance compensation equal to six months of salary. Effective April 1, 2019, Mr. Andrade's salary was increased to $290,000 per year.

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

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

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

Payments on Termination

The following table provides details regarding the estimated incremental payments from the Corporation to each of the current Named Executive Officers assuming termination without cause on December 31, 2019.

Name	Severance	Estimated Bonus	Value of benefits
Rostislav Raykov, CEO	$ 400,000	$ -	$ 400,000
Robert Andrade, CFO	$ 145,000	$ -	$ 145,000
Shubh Goel, CCO	$ 90,000	$ 115,000	$ 205,000

Payments on Change of Control

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

Name	Change of Control Multiple	Estimated Bonus[(1)]	Value of benefits
Rostislav Raykov, CEO	2 X	$ 1,070,000	$ 1,070,000
Robert Andrade, CFO	1.25 X	$ 453,500	$ 453,500

(1) Change of control payments are calculated based on the two-year annualized average salary plus cash bonus as calculated as of December 31, 2019.

In addition to the payments above, an incentive plan has been established pursuant to which, upon completion of a change in control transaction, 1% of the transaction value (up to a maximum of $2,000,000) be set aside and paid to key personnel upon completion of such change in control transaction, with 50% of such incentive pool being payable to the CEO and the balance to other key personnel as determined by the CEO in consultation with the Compensation Committee.

Equity Grants, Exercises and Holdings

The following table sets forth information concerning the number and value of unexercised options held by each Named Executive Officer as of December 31, 2019. All executive awards, with the exception of those expiring 6/27/2027, 02/06/2028 and 04/04/2029 vest and are exercisable immediately. The current stock option plan provides for grants denominated in US and CAD dollars.

	Number of Options				
Name	Granted	Exercisable	Option Exercise Price		Expiration Date
Rostislav Raykov	150,000	-	USD$	4.83	04/04/2029
	100,000	63,888	USD$	8.38	02/06/2028
	100,000	83,336	USD$	5.10	06/27/2027
	150,000	150,000	USD$	2.45	07/05/2026
	25,000	25,000	USD$	2.69	12/31/2024
	83,333	83,333	USD$	1.59	01/24/2024
	16,666	16,666	USD$	0.72	08/23/2023
	50,000	50,000	USD$	1.05	11/20/2022
	323,961	323,961	CAD$	2.43	08/18/2020
Robert Andrade	80,000	-	USD$	4.83	04/04/2029
	50,000	31,843	USD$	8.38	02/06/2028
	50,000	41,668	USD$	5.10	06/27/2027
	75,000	75,000	USD$	2.45	07/05/2026
	323,961	323,961	CAD$	2.43	08/18/2020
Shubh Goel	175,000	-	USD$	4.74	09/09/2029

Compensation of Directors

Director Compensation Table

The following table summarizes the compensation earned by our non-executive directors for the year ended December 31, 2019.

Name	Fees paid in Cash	Stock Awards	Option Awards[1][2]	Total
Dr. Islam	85,000	–	105,190	190,190
Mr. Brughera	40.000	–	84,152	124,152
Mr. Haigh	40,000	–	84,152	124,152
Dr. Cook	9,421	–	103,013	112,434
Mr. Rallis	42,500	–	84,152	126,652
Total	**$ 216,921**	**$ –**	**$ 460,659**	**$ 677,580**

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

Name	Date of Grant	Number of Options Granted	Option Exercise Price $USD
Mr. Rallis	June 18, 2019	20,000	4.26
Mr. Brughera	June 18, 2019	20,000	4.26
Mr. Haigh	June 18, 2019	20,000	4.26
Dr. Islam	June 18, 2019	25,000	4.26
Jodi Cook	November 13, 2019	20,000	5.40
Total		**105,000**	

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

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

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

The following table sets forth information regarding our common shares beneficially owned as of February 11, 2020 by: (i) each of our officers and directors; (ii) all officers and directors as a group; and (iii) each person known by us to beneficially own five percent or more of our outstanding common shares. Except as indicated below, the security holders listed possess sole voting and investment power with respect to the shares beneficially owned by that person. Except as otherwise indicated below, the address for each listed shareholder is c/o Fennec Pharmaceuticals Inc., 68 TW Alexander Drive, PO Box 13628, Research Triangle Park, North Carolina 27709.

Name	Common shares	Common shares Options Exercisable Within 60 Days	Common shares Purchase Warrants Exercisable Within 60 Days	Total Stock and Stock Based Holdings[1]	% Ownership[1]
Adrian J. Haigh	–	213,579	-	213,579	1.06%
Dr. Khalid Islam	–	288,825	–	288,825	1.43%
Robert Andrade	17,050	578,961	–	596,011	2.91%
Marco Brughera	–	95,545	–	95,545	0.48%
Jodi Cook	-	20,000	-	20,000	0.10%
Chris A. Rallis	–	171,850	–	171,850	0.86%
Shubh Goel	-	175,000	-	175,000	5.06%
Rostislav Raykov	57,790	998,960	–	1,056,750	11.67%
All Officers and Directors as a Group	**74,840**	**2,542,720**	–	**2,617,560**	**11.67%**
Southpoint Capital Advisors, LP.[2]	3,997,214	–	–	3,997,214	20.09%
Essetifin SpA[3]	3,225,694	–	–	3,225,694	16.21%
venBio Select Fund LLC[4]	1,105,999	-	-	1,105,999	5.56%

(1) For purposes of this table "beneficial ownership" is determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, pursuant to which a person or group of persons is deemed to have "beneficial ownership" of any common shares that such person or group has the right to acquire within 60 days after February 11, 2020. For purposes of computing the percentage of outstanding common shares held by each person or group of persons named above, any shares that such person or group has the right to acquire within 60 days after February 11, 2020 are deemed outstanding but are not deemed to be outstanding for purposes of computing the percentage ownership of any other person or group. As of February 11, 2020, there were 19,895,830 common shares issued and outstanding.
(2) Southpoint Capital Advisors, LP, 623 Fifth Avenue, Suite 2503, New York, New York 10022. John S. Clark, II holds dispositive power over the shares owned by Southpoint Capital Advisors, LP.
(3) Essetifin SpA, Via Sudafrica 20, Rome, Italy 00144. Mario Artali holds dispositive power over the shares owned by Essetifin SpA.
(4) venBio Select Fund LLC, 110 Greene Street, Suite 800, New York, NY 10012. Scott Esptein holds dispositive power over the shares held by venBio Select Fund LLC

Equity Compensation Plan Information

The following table provides certain information with respect to securities authorized for issuance under equity incentive plans as of December 31, 2019 (share amounts are in thousands):

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column (a))
Equity compensation plans approved by security holders	3,127	USD $ 3.63*	1,886
Total	**3,127**	–	**1,886**

* Our current stock option plans allow for the issuance of stock options denominated in both U.S. dollars and Canadian dollars. This table presents the number and weighted-average exercise price of outstanding options by the currency associated with the original grants. At December 31, 2019, we had outstanding options to purchase 2.44 million of our common shares denominated in U.S. dollars with a weighted-average exercise price of $4.05 and outstanding options to purchase 648,000 of our common shares denominated in CAD dollars with a weighted-average exercise price of CAD$2.43 (for total outstanding options to purchase 3.10 million of our common shares with a combined weighted-average exercise price of USD$3.59 with Canadian denominated exercise prices converted using the December 31, 2019 exchange rate of 0.7682 CAD/USD). At December 31, 2019, there were 1.89 million common shares available for future grants under our current stock option plan. There were also 0.04 million warrants outstanding with an exercise price of $6.80.

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

Related Party Transactions

There were no reportable transactions with related parties during the year ended December 31, 2019 in which the amount involved exceeded the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years.

Director Independence

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

Item 14. Principal Accounting Fees and Services

The following presents the aggregate fees for professional services and other services rendered by our independent auditors, Haskell & White LLP in fiscal year 2019 and 2018:

	Fiscal Year 2019	Fiscal Year 2018
Audit Fees[1]	74,500	76,006
Audit-Related Fees[2]	–	–
Tax Fees[3]	–	–
All Other Fees[4]	2,500	–
Total	**$ 77,000**	**$ 76,006**

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

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are included as part of this Annual Report filed on Form 10-K:

1. Financial Statements – See Index to Financial Statements on page F-1.

2. All schedules are omitted as the information required is inapplicable or the information is presented in the financial statements.

3. Exhibits:

Exhibit No.	Description	Location
3.1	Notice of Articles dated August 25, 2011	Exhibit 3.2I to the Form 8-K of the Company filed August 26, 2011
3.2	Articles dated August 25, 2011	Exhibit 3.2II to the Form 8-K of the Company filed August 26, 2011
3.3	Notice of Alteration Dated September 3, 2014	Exhibit 3.1 to the Form 8-K of the Company filed September 9, 2014
10.1	Fennec Amended and Restated Stock Option Plan*	Exhibit 10.1 to the Form 8-K of the Company filed September 29, 2017
10.2	Executive Employment Agreement dated May 3, 2010 by and between Fennec and Rostislav Raykov*	Exhibit 10.28 to the Form 10-Q of the Company filed May 14, 2010
10.3	Form of Independent Director Agreement, dated May 3, 2010	Exhibit 10.31 to the Form 10-Q of the Company filed May 14, 2010
10.4	Form of Subscription Agreement from June 8, 2017 Private Placement	Exhibit 10.15 to the Form S-1 of the Company filed August 10, 2017
10.5	Subscription Agreement, dated November 15, 2013, between the Company, Technologies Inc. and Manchester Management LLC	Exhibit 10.19 to the Form 10K/A of the Company filed April 2, 2014
10.6	Form of Subscription Agreement from December 3, 2014 private placement	Exhibit 10.20 to the Form 10K of the Company filed March 31, 2015
10.7	Executive Employment Agreement dated November 12, 2015 by and between Fennec and Robert Andrade*	Exhibit 10.40 to the Form 10-Q of the Company filed November 12, 2015
10.8	Subscription Agreement, dated April 8,2016, between Fennec Pharmaceuticals Inc. and Sigma Tau Finanzaria	Exhibit 10.41 to the Form 10-Q of the Company filed May 12, 2016
10.9	Purchase Agreement, dated May 9, 2016, between Fennec Pharmaceuticals Inc. and Elion Oncology, LLC.	Exhibit 10.42 to the Form 10-Q of the Company filed May 12, 2016
10.10	Loan and Security Agreement dated as of February 1, 2019 by and between Fennec Pharmaceuticals, Inc. and Western Alliance Bank	Exhibit 10.1 to the Form 8-K of the Company filed February 4, 2019
16.1	Letter Regarding Change in Certifying Accountant	Exhibit 16.1 to the Form 8-K of the Company filed May 17, 2017
21	Subsidiaries	Filed herewith

Exhibit No.	Description	Location
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
99.1	Press Release for Fiscal Year Ended December 31, 2019	Filed herewith
101.1	Interactive Data File	Filed herewith

* Indicates a management contract or compensatory plan.

** The Company has received confidential treatment with respect to certain portions of this exhibit. Those portions have been omitted from this exhibit and are filed separately with the U.S. Securities and Exchange Commission.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Fennec Pharmaceuticals Inc.

By: /s/ Rostislav Raykov

Rostislav Raykov
Chief Executive Officer and Director

Date: February 14, 2020

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

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

Signatures	Title	Date
/s/ Rostislav Raykov **Rostislav Raykov**	Chief Executive Officer (principal executive officer) and Director	February 14, 2020
/s/ Robert Andrade **Robert Andrade**	Chief Financial Officer (principal financial officer and principal accounting officer)	February 14, 2020
/s/ Adrian J. Haigh **Adrian J. Haigh**	Director	February 14, 2020
/s/ Dr. Khalid Islam **Dr. Khalid Islam**	Director	February 14, 2020
/s/ Chris A. Rallis **Chris A. Rallis**	Director	February 14, 2020
/s/ Marco Brughera **Marco Brughera**	Director	February 14, 2020
/s/ Jodi Cook **Jodi Cook**	Director	February 14, 2020

FENNEC PHARMACEUTICALS INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors and
Fennec Pharmaceuticals Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Fennec Pharmaceuticals Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/Haskell & White LLP
HASKELL & WHITE LLP

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

Irvine, California
February 14, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 13,650	$ 22,781
Prepaid expenses	226	168
Other current assets	8	1
	13,884	22,950
Non-Current assets		
Deferred issuance cost	326	-
Deferred issuance cost (amortization)	(64)	-
	262	-
Total assets	$ 14,146	$ 22,950
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,612	$ 1,032
Accrued liabilities	659	605
Total current liabilities	2,271	1,637
Total liabilities	2,271	1,637
Commitments and Contingencies (Note 9)		
Shareholders' equity:		
Common stock, no par value; unlimited shares authorized; 19,896 shares issued and outstanding (2018-19,896)	106,392	106,392
Additional paid-in capital	48,271	44,934
Accumulated deficit	(144,031)	(131,256)
Accumulated other comprehensive income	1,243	1,243
Total shareholders' equity	11,875	21,313
Total liabilities and shareholders' equity	$ 14,146	$ 22,950

(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, 2019	**December 31, 2018**
Revenue	$ -	$ -
Operating expenses:		
Research and development	5,607	5,008
General and administrative	7,402	5,401
Loss from operations	(13,009)	(10,409)
Other income/(expense):		
Unrealized gain/(loss) on derivatives (Note 5)	-	167
Amortization expense	(64)	-
Other income/(loss)	(17)	6
Net interest income	315	348
Total other income/(loss), net	234	521
Net loss	$ (12,775)	$ (9,888)
Loss per common share, basic and diluted	$ (0.64)	$ (0.52)
Weighted-average number of common shares outstanding basic and diluted (Note 3)	19,896	18,942

(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, 2019	December 31, 2018
Cash flows (used in) provided by:		
Operating activities:		
Net loss	$ (12,775)	$ (9,888)
Adjustments to reconcile net (loss) to net cash used in operating activities:		
Unrealized (gain)/loss on derivatives	-	(167)
Amortization of deferred issuance costs	64	-
Stock-based compensation - consultants	417	272
Stock-based compensation - employees	2,665	1,825
Changes in operating assets and liabilities:		
Prepaid expenses	(58)	(40)
Other assets	(7)	12
Accounts payable	580	177
Accrued liabilities	54	(17)
Net cash used in operating activities	(9,060)	(7,826)
Financing activities:		
Cash paid for issuance costs	(71)	-
Short swing profit judgment offset with settlement expense	-	18
Issuance of shares, options exercise	-	210
Issuance of shares, warrants exercise	-	2,119
Net cash (used in)/provided by financing activities	(71)	2,347
Increase in cash and cash equivalents	(9,131)	(5,479)
Cash and cash equivalents - Beginning of year	22,781	28,260
Cash and cash equivalents - End of year	$ 13,650	$ 22,781
Non-cash deferred issuance cost (warrant value)	$ 255	$ -

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

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

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Number (Note 7)	Amount	Capital	Deficit	Income	Equity
Balance at December 31, 2017	18,411	103,045	43,837	(121,368)	1,243	26,757
Short swing profit judgment offset with settlement expense	-	-	18	-	-	18
Stock options issued to consultants	-	-	272	-	-	272
Stock options issued to employees	-	-	1,825	-	-	1,825
Exercise of stock options	122	436	(226)	-	-	210
Exercise of warrants	1,363	2,911	(792)	-	-	2,119
Net loss	-	-	-	(9,888)	-	(9,888)
Balance at December 31, 2018	**19,896**	**$ 106,392**	**$ 44,934**	**$ (131,256)**	**$ 1,243**	**$ 21,313**
Stock options issued to consultants	-	-	417	-	-	417
Stock options issued to employees	-	-	2,665	-	-	2,665
Warrants issued to consultants	-	-	255	-	-	255
Net loss	-	-	-	(12,775)	-	(12,775)
Balance at December 31, 2019	**19,896**	**$ 106,392**	**$ 48,271**	**$ (144,031)**	**$ 1,243**	**$ 11,875**

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

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

1. Nature of Business and Liquidity

Fennec Pharmaceuticals Inc. ("Fennec," "the Company," "we," "us," or "our") was originally formed as a British Columbia corporation under the name Adherex Technologies Inc. and subsequently changed its name on September 3, 2014. Fennec, together with its wholly owned subsidiaries Oxiquant, Inc. ("Oxiquant") and Fennec Pharmaceuticals, Inc., both Delaware corporations, and Cadherin Biomedical Inc. ("CBI"), a Canadian corporation and Fennec Pharmaceuticals (EU) Limited ("Fennec Limited"), collectively referred to herein as the "Company," is a biopharmaceutical company with a product candidate under development for use in the treatment of cancer. With the exception of Fennec Pharmaceuticals, Inc., all subsidiaries are inactive.

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

During the year ended December 31, 2019, the Company incurred a net loss from operations of $12,775 and still has not earned any revenue in its history. At December 31, 2019 it had an accumulated deficit of $144,031 and had experienced negative cash flows from operating activities in the amount of $9,060 for the year ended December 31, 2019.

On February 1, 2019, Fennec entered into a Loan and Security Agreement with Bridge Bank, a division of Western Alliance Bank, an Arizona corporation, pursuant to which the Bank agreed to loan $12.5 million to the Company, to be made available upon New Drug Application NDA approval of PEDMARK by no later than September 30, 2020. The proceeds from the loan will be used for working capital purposes and to fund general business requirements in accordance with the terms of the Loan and Security Agreement. Interest under the Term Loans shall bear interest, on the outstanding daily balance thereof, at a floating per annum rate equal to the Effective Interest Rate (as defined in the Loan and Security Agreement) which is equal to the sum of the Prime Rate published in the Wall Street Journal (currently 4.75%) plus one percent (1.00%). The debt facility is to have interest-only monthly payments due for the first eighteen months from the funding date and then monthly principal and interest payments are due through the remainder of the term which has a maturity date of October 1, 2023. In connection with the facility, Fennec has agreed to grant Bridge Bank a warrant to purchase up to 39,130 common shares at an exercise price of $6.80 per common share, for a term of ten years from the date of issuance, subject to early termination under certain conditions.

The Company believes the aforementioned raise, along with the current cash on hand, provides sufficient funding for the Company to carry-out its planned activities for the next fifteen to eighteen months as it continues its strategic development of PEDMARK™.

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

2. Significant Accounting Policies

Basis of presentation

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

Use of estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expense during the reporting period. Significant estimates include the valuation of derivative warrant liability and the valuation of stock-based compensation. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

The Company places its cash and cash equivalents in investments held by highly rated financial institutions in accordance with its investment policy designed to protect the principal investment. At December 31, 2019, the Company had $13.7 million in cash and money market accounts (2018- $22.8 million). Money market investments typically have minimal risks. The Company has not experienced any loss or write-down of its money market investments.

Financial instruments

Financial instruments recognized on the balance sheets at December 31, 2019 and December 31, 2018 consist of cash and cash equivalents, accounts payable and accrued liabilities, the carrying values of which, approximate fair value due to their relatively short time to maturity. The Company does not hold or issue financial instruments for trading.

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

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

Common shares and warrants

The Company has warrants outstanding to purchase common shares that were denominated in both United States dollars ("USD") and Canadian dollars ("CAD"), which resulted in the Company having warrants outstanding that were denominated outside of the Company's U.S. dollar functional currency.

The Company's outstanding warrants denominated in Canadian dollars were not considered to be indexed to the Company's own stock and should therefore be treated as derivative financial instruments and recorded at their fair value as a liability. During the year ended December 31, 2018, all warrants accounted for as derivatives were exercised. These exercises reduced the derivative liability to $0 as of December 31, 2018. At December 31, 2017, the derivative liabilities were valued at approximately $167,000. There was an unrealized, non-cash gain on derivative liabilities of approximately $167,000 upon expiry for the year ended December 31, 2018.

Revenue recognition

At this time, the Company does not have any revenue.

Research and development costs and investment tax credits

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

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

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, 2019, we maintained a full valuation allowance against our deferred tax assets.

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

Foreign currency translation

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

Loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the year. Diluted net earnings per share is computed using the same method, except the weighted average number of common shares outstanding includes convertible debentures, stock options and warrants, if dilutive, as determined using the if-converted method and treasury methods. Accordingly, warrants to purchase 0.04 million of our common shares and options to purchase 3.1 million of our common shares at December 31, 2019, were not included in earnings per share. Such options would have an antidilutive effect. In 2018, options to purchase 2.5 million common shares were excluded from the computation of earnings per share as their inclusion would have been antidilutive.

Recent accounting pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 removes certain disclosures, modifies certain disclosures and adds additional disclosures. The ASU is effective for us on January 1, 2020, and interim periods within that fiscal year. Early adoption is permitted. Certain disclosures in ASU 2018-13 would need to be applied on a retrospective basis and others on a prospective basis. The Company concluded after evaluation that ASU 2018-13 will have no significant effect on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, to include share-based payment transactions for acquiring goods and services from nonemployees. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. We adopted this policy as of January 1, 2019. The Company concluded after evaluation that the impact of ASU 2018-07 on our consolidated financial statements and disclosures was de minimis.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new guidance requires the recognition of lease liabilities, representing future minimum lease payments, on a discounted basis, and corresponding right-of-use assets on a balance sheet for most leases, along with requirements for enhanced disclosures to give financial statement users the ability to assess the amount, timing and uncertainty of cash flows arising from leasing arrangements. In July 2018, the FASB issued ASU 2018-10 and 2018-11 which permit application of the new guidance at the beginning of the year of adoption, recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, in addition to the method of applying the new guidance retrospectively to each prior reporting period presented. The ASU was effective for us on January 1, 2019. We concluded the impact of this guidance is negligible on our consolidated financial statements, given we have no material leases.

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, 2019	**December 31, 2018**
Numerator:		
Net loss	$ (12,775)	$ (9,888)
Denominator:		
Weighted-average common shares, basic	19,896	18,942
Dilutive effect of stock options	–	–
Dilutive effect of warrants	–	–
Incremental dilutive shares	–	–
Weighted-average common shares, diluted	19,896	18,942
Net loss per share, basic and diluted	**$ (0.64)**	**$ (0.52)**

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

	Year Ended	
	December 31, 2019	December 31, 2018
Options to purchase common shares	3,088	2,498
Warrants to purchase common shares	39	-

4. Stock options

The Compensation Committee of the Board of Directors administers the Company's stock option plan. The Compensation Committee designates eligible participants to be included under the plan and approves the number of options to be granted from time to time under the plan. On June 24, 2010, at the Company's annual meeting, shareholders approved an amendment to the Company's Stock Option Plan (the "Plan Maximum Amendment"). The Plan Maximum Amendment relates to changing the maximum number of common shares issuable under the stock option plan from a fixed number of 6.7 million to the number of shares that represents twenty-five percent (25%) of the total number of all issued and outstanding common shares. Based upon the current shares outstanding, a maximum of 5.0 million of our common shares are authorized for issuance under the plan. The option exercise price for all options issued under the plan is based on the fair value of the underlying shares on the date of grant. All options vest within three years or less and are exercisable for a period of ten years from the date of grant. The stock option plan, as amended, allows the issuance of Canadian and U.S. dollar grants. A summary of the stock option transactions, for both the Canadian and U.S. dollar grants, through the year ended December 31, 2019 is below.

Summary of $CAD Option Activity

Share Prices Reported in $CAD	Number of Options (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2017	**712**	**$ 1.89 – 2.43**	**$ 2.38**
Exercised	(64)	1.89 – 2.43	1.83
Outstanding and exercisable at December 31, 2018	**648**	**$ 2.43**	**$ 2.43**
Outstanding and exercisable at December 31, 2019	**648**	**$ 2.43**	**$ 2.43**

Summary of $CAD Option Remaining Life

Price $CAD	Outstanding and Exercisable at December 31, 2019 (in thousands)	Weighted Average Remaining Life (years)
$ 2.43	648	0.63

Summary of $USD Option Activity

	Number of Options (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2017	**1,603**	**$ 0.45 – 10.10**	**$ 2.70**
Granted	305	8.38 – 12.59	9.23
Exercised	(58)	1.05 – 3.67	2.06
Outstanding and exercisable at December 31, 2018	**1,850**	**$ 0.45 – 12.59**	**$ 3.80**
Granted	590	4.26 – 5.91	4.83
Outstanding and exercisable at December 31, 2019	**2,440**	**$ 0.45 – 12.59**	**$ 3.59**

Summary of $USD Option Remaining Life

Price in US Dollars	Number Outstanding and Exercisable at December 31, 2019 (in thousands)	Remaining Life (years)
$ 0.45	11	2.63
$ 0.54	19	2.38
$ 0.60	17	2.26

Price in US Dollars	Number Outstanding and Exercisable at December 31, 2019 (in thousands)	Remaining Life (years)
$ 0.72	50	3.65
$ 0.96	10	3.60
$ 1.05	93	2.89
$ 1.13	50	5.95
$ 1.23	8	5.87
$ 1.50	7	1.88
$ 1.59	133	4.07
$ 2.11	36	7.00
$ 2.30	4	5.36
$ 2.31	275	4.32
$ 2.35	4	5.59
$ 2.40	8	3.26
$ 2.44	49	6.44
$ 2.45	285	6.52
$ 2.51	4	5.21
$ 2.55	4	4.86
$ 2.69	114	5.01
$ 2.79	22	4.60
$ 2.94	3	3.38
$ 3.10	10	7.26
$ 3.60	3	4.38
$ 3.67	35	7.38
$ 4.26	85	9.47
$ 4.74	175	9.74
$ 4.83	260	9.27
$ 5.10	250	7.49
$ 5.40	20	9.88
$ 5.91	50	10.00
$ 6.72	21	7.63
$ 8.38	210	8.11
$ 10.10	20	7.88
$ 10.93	85	8.44
$ 12.59	10	8.26
Total	**2,440**	**6.79**

Stock compensation expense for the fiscal years ended December 31, 2019 and 2018 was $3.1 million and $2.1 million respectively. These amounts have been included in the general and administrative expenses for the respective periods. The weighted average fair value per share of options granted and or vested during the fiscal years ended December 31, 2019 and 2018 was $4.83 and $9.12, respectively. The intrinsic value (being the difference between the share price at December 31, 2019 and exercise price) of stock options exercisable at December 31, 2019 was $9.1 million. The intrinsic value of options exercised during the fiscal year ended December 31, 2019 was $0.0 million. The fair value of all options vested during the fiscal year ended December 31, 2019 was $2.1 million.

The fair values of options granted in fiscal years ended December 31, 2019 and 2018 were estimated on the date the options were granted based on the Black-Scholes option-pricing model, using the following weighted average assumptions for all options with a ten-year expiration:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Expected dividend	0%	0%
Risk-free interest rate	1.63– 2.70%	2.53– 3.00%
Expected volatility	125 – 179%	132 – 151%
Expected life	4.3 – 10.0 years	4.5 – 7 years

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

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

Modification of Existing US Dollar Denominated Options

In 2019, the Company modified the terms of all outstanding US denominated options extending the expiration date by a weighted average amount of 2.98 years. The Company recorded option modification expense of approximately $1.34 million in the year ended December 31, 2019, included in the $3.1 million of stock compensation in general and administrative expense, discussed above. Some of the option grants were not fully vested, as a result, the Company will recognize $0.1 million in expense over the next nine quarters. The following table summarizes the effect of the June 18, 2019 transaction:

Exercise Price $USD	Number of Options	Expiration Date	Risk Free Rate	Expected Life (Years)	Volatility	Expense Recognized $USD 6/18/19	Expense Recognized $USD After 6/18/19
0.45	11,111	08/17/2022	2.20%	3.16	71%	475	-
0.54	9,259	05/17/2022	2.04%	2.91	67%	670	-
0.60	8,333	04/04/2022	2.04%	2.80	68%	732	-
0.72	16,666	08/23/2023	2.04%	4.18	125%	20,642	-
0.96	3,063	08/06/2023	2.04%	4.13	126%	6,126	-
1.05	4,762	11/20/2022	2.04%	3.43	73%	1,886	-
1.05	83,333	11/20/2022	2.04%	3.43	73%	18,566	-
1.13	50,000	12/11/2025	1.80%	6.48	130%	33,193	-
1.23	4,062	11/10/2025	1.80%	6.40	131%	5,988	-
1.50	6,666	11/18/2021	2.20%	2.42	66%	2,247	-
1.59	132,954	01/24/2024	1.86%	4.60	122%	139,829	-
2.11	35,545	12/30/2026	1.83%	7.53	133%	12,331	-
2.30	4,346	05/11/2025	1.80%	5.90	127%	5,475	-
2.31	275,324	04/25/2024	1.86%	4.85	123%	404,154	-
2.35	4,254	08/03/2025	1.80%	6.13	133%	5,346	-
2.40	8,332	04/03/2023	2.04%	3.79	130%	13,640	-
2.44	49,180	06/06/2026	1.80%	6.98	136%	19,729	-
2.45	285,000	07/05/2026	1.83%	7.05	136%	114,692	526
2.51	3,984	03/16/2025	1.80%	5.74	127%	5,401	-
2.55	3,920	11/07/2024	1.86%	5.39	124%	5,529	-
2.69	114,000	12/31/2024	1.80%	5.54	125%	164,445	-
2.79	21,790	08/04/2024	1.86%	5.13	125%	35,363	-
2.94	3,400	05/17/2023	2.04%	3.91	129%	6,633	-
3.10	10,000	05/15/2024	1.83%	7.79	132%	3,839	-
3.60	2,778	04/03/2027	1.86%	4.91	123%	5,609	-
3.67	35,000	05/17/2027	1.83%	7.91	133%	14,951	-
4.83	260,000	04/04/2028	1.93%	9.80	153%	5,099	59,074
5.10	250,000	06/27/2027	1.83%	8.02	132%	94,204	26,291
6.72	21,150	08/17/2027	1.83%	8.16	131%	10,298	-
8.38	210,000	02/06/2028	1.83%	8.64	146%	58,434	67,273
10.10	20,000	11/16/2027	1.83%	8.41	137%	12,193	-
10.93	85,000	06/08/2028	1.83%	8.97	149%	51,289	-
12.59	10,000	04/03/2028	1.83%	8.79	147%	6,366	-
	2,1102,313					**1,285,374**	**153,064**

Modification of Existing Canadian Dollar Denominated Options

In 2018, the Company modified the terms of certain options granted to executives and directors by extending the expiration date by a weighted average amount of 2.0 years. The Company recorded option modification expense of approximately $112,000 included in general and administrative expense. The expense was calculated using the Black-Scholes valuation method with a June 7, 2018 exchange rate of $CAD/$USD 0.7715. The following table summarizes the effect of the June 7, 2018 transaction:

Number of Options	Expiration Date	Risk Free Rate	Exercise Price $CAD	Share Price $CAD	Expected Life (Years)	Volatility	Expense Recognized $USD
648	08/18/2020	1.90%	2.43	14.14	2.2	76%	112
648							**112**

5. Derivative Liabilities

The Company's derivative instruments on January 1, 2018 included options to purchase 19,441 common shares, the exercise prices for which are denominated in a currency other than the Company's functional currency, as follows:

- Contractor options to purchase 17,394 common shares exercisable at CAD$1.62 per whole common share that expire on April 4, 2018;
- Contractor options to purchase 2,047 common shares exercisable at CAD$2.43 per whole common share that expire on May 18, 2018.

During the year ended December 31, 2018, all of these derivative options were exercised. This resulted in gross proceeds of $26,109, the issuance of 19,441 common shares and a non-cash, realized gain on the extinguishment of the remaining derivative liability of $167,131.

During the fiscal years ended December 31, 2011 and 2010, the Company issued 35,892 and 28,796, respectively, options to contractors with a Canadian dollar denominated strike price. Consequently, the Company had derivatives relating to these options since the strike price is denominated in a currency other than the US dollar functional currency of the Company. While there is an exception to this rule for employees in ASU 2010-13 "Compensation-Stock Compensation (Topic 718): Effect of Denominating the exercise price of a share-based payment award in the currency of the market in which the underlying equity security trades", no such exception exists for contractors. These options were marked to market until the earlier of their expiry or exercise. All Canadian denominated options issued to contractors fully vested at issuance and were to expire seven years from date of issuance. The fair value of these options at December 31, 2019 and December 31, 2018 was $0. The unrealized gain for these options for the year ended December 31, 2018 was $167,131.

The following is a summary of Canadian denominated contractor option activity for the year ended December 31, 2018 and 2019.

Share Prices Reported in $CAD	Number of Options Outstanding and Exercisable (in thousands)	Weighted Average Exercise Price
Outstanding and exercisable at December 31, 2017	**19**	**$ 1.71**
Exercised	**(19)**	**$ 1.71**
Outstanding and exercisable at December 31, 2018	**–**	**–**
Outstanding and exercisable at December 31, 2019	–	–

The following table presents gain on change in derivative valuation for the year ended December 31, 2019 and December 31, 2018:

Derivative Warrants/Options	Gain (in thousands) on Derivative Instruments at December 31, 2019	2018
Options (various expiration dates)	-	167
Total	**-**	**167**

6. 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.

Assets/Liabilities Measured at Fair Value on a Recurring Basis

	Fair Value Measurement at December 31, (in thousands)							
	Quoted Price in Active Market for Identical Instruments		Significant Other Observable Inputs		Significant Unobservable Inputs			
	Level 1		Level 2		Level 3		Total	
	2019	2018	2019	2018	2019	2018	2019	2018
Assets								
Cash and cash equivalents	347 (1)	770 (1)	13,303	22,011	-	-	13,650	22,781

(1) The Company held approximately, $347,000 in cash as of December 31, 2019, of which approximately, $30,000 was in Canadian funds (translated into U.S. dollars). As of December 31, 2018, the Company held approximately $770,000, of which approximately 121,000 was in Canadian funds (translated into U.S. dollars).

7. Stockholders' Equity

Authorized capital stock

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

Warrants to Purchase Common Shares

At December 31, 2019, the Company had 39,130 warrants outstanding to purchase common shares at an exercise price of $6.80. The following table summarized our warrant activity.

	Number of Warrants (in thousands)	Range	Weighted Average
Outstanding and exercisable at December 31, 2017	**1,612**	**$ 1.50 – 3.00**	**$ 1.56**
Exercised	(1,612)	**$ 1.50 – 3.00**	**$ 1.56**
Outstanding and exercisable at December 31, 2018	**-**	**-**	**-**
Granted	39	**$ 6.80**	$ 6.80
Outstanding and exercisable at December 31, 2019	**39**	**$ 6.80**	$ 6.80

8. Related Party Transactions

In the second quarter of 2018, the Company recorded approximately $25 related to the net recovery of short-swing profits from one of the Company's shareholders under Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these related party proceeds, net of $7 related legal fees and taxes, as an increase to additional paid-in capital consolidated balance sheet as of December 31, 2018, as well as cash proceeds of approximately $18 as cash provided by financing activities in the consolidated statement of cash flows for the period ended December 31, 2018.

9. Commitments and Contingencies

Oregon Health & Science University Agreement

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

On May 18, 2015, Fennec negotiated an amendment ("Amendment 1") to the OHSU Agreement, which expands Fennec's exclusive license to include the use of N-acetylcysteine as a standalone therapy and/or in combination with STS for the prevention of ototoxicity induced by chemotherapeutic agents to treat cancers. Further, Amendment 1 adjusts select milestone payments entered in the OHSU Agreement including but not limited to the royalty rate on net sales for licensed products, royalty rate from sublicensing of the licensed technology and the fee payable upon the regulatory approval of a licensed product.

The term of the OHSU Agreement as amended by Amendment 1 expires on the date of the last to expire claim(s) covered in the patents licensed to Fennec or 8 years, whichever is later. In the event a licensed product obtains regulatory approval and is covered by the Orphan Drug Designation, the parties will in good faith amend the term of the agreement. STS is currently protected by methods of use patents that the Company exclusively licensed from OHSU that expire in Europe in 2021 and are currently pending in the United States. The OHSU Agreement is terminable by either Fennec or OHSU in the event of a material breach of the agreement by either party after 45 days prior written notice. Fennec also has the right to terminate the OHSU Agreement at any time upon 60 days prior written notice and payment of all fees due to OHSU under the OHSU Agreement.

Executive Severance

In the event of his termination with us other than for cause, we will be obligated to pay Mr. Raykov a one-time severance payment equal to twelve months of salary (currently $400,000). In the event of his termination with us other than for cause, we will be obligated to pay Mr. Andrade a one-time severance payment equal to six months of salary (currently $145,000).

10. Subsequent Events

On February 11, 2020, Fennec announced it had completed its rolling submission of aNew Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) forPEDMARK™ (sodium thiosulfate anhydrous injection) for intravenous use.

Management has evaluated subsequent events through February 14, 2020, the date the financial statements were available to be issued and has concluded there are no additional events that would require adjustment to our disclosure in the statements.

11. Income Taxes

The Company operates in both U.S. and Canadian tax jurisdictions. Its income is subject to varying rates of tax and losses incurred in one jurisdiction cannot be used to offset income taxes payable in another. A reconciliation of the combined Canadian federal and provincial income tax rate with the Company's effective tax rate is as follows (in thousands except for percentage rates):

	Year Ended December 31, 2019	Year Ended December 31, 2018
Domestic (loss)/gain	$ (9,004)	$ (7,702)
Foreign loss	(3,734)	(2,145)
Loss before income taxes	(12,738)	(9,847)
Expected statutory rate (recovery)	26.50%	26.50%
Expected provision for (recovery of) income tax	(3,376)	(2,609)
Permanent differences	901	512
Change in valuation allowance	2,193	2,042
Effect of foreign exchange rate differences	–	–
Effect of change in future enacted tax rates	–	–
Tax credits and other adjustments	–	–
Effect of tax rate changes and other	280	55
Provision for income taxes	$ -	$ -

The Canadian statutory come tax rate of 26.0 percent is comprised of federal income tax at approximately 15.0 percent and provincial income tax at approximately 11.0 percent.

The primary temporary differences which gave rise to future income taxes (recovery) at December 31, 2019 and December 31, 2018:

	December 31, 2019	December 31, 2018
Future tax assets:		
SR&ED expenditures	$ 2,086	$ 2,195
Income tax loss carryforwards	23,182	21,452
Non-refundable investment tax credits	1,121	1,250
Share issue costs	99	45
Accrued expenses	–	–
Fixed and intangible assets	1,083	1,065
Reserves	-	13
	27,572	26,020
Less: valuation allowance	(27,572)	(26,020)
Net future tax assets	$ –	$ –

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

Tax Cuts and Jobs Act

On December 22, 2017, the United States government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and jobs Act (the “Tax Act”). The Tax Act reduces the corporate tax rate to 21%, effective January 1, 2018. The Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 (“SAB 118”) on December 23, 2017. SAB 118 provides a one-year measurement period from a registrant’s reporting period that includes the United States Tax Act’s enactment date to allow the registrant sufficient time to obtain, prepare and analyze information to complete the accounting required under ASC 740. The ultimate impact of the Tax Act on our reported results may differ from the estimates provided herein, possibly material, due to, among other things, changes in interpretations and assumptions we have made, guidance that may be issued, and other actions we may take as a result of the Tax Act different from presently contemplated.

There are no current income taxes owed, nor are any income taxes expected to be owed in the near term. At December 31, 2019 the Company 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):		
2020	-	6,169
2021	26	2,716
2022	233	4,219
2023	1,588	4,164
2024	4,849	2,116
2025	17,229	11,786
2026	6,690	4,698
2027	10,555	6,980
2028	10,250	6,724
2029	3,916	2,416
2030	3,243	3,376
2031	3,675	3,746
2032	1,755	996
2033	1,782	3,149
2034	1,685	4,600
2035	2,131	1,189
2036	3,901	2,882
2037	7,024	5,267
2038	5,687	5,687
No expiration	5,899	-
Investment tax credits (expiry date):		
2019	91	
2020	52	
2021	521	
2022	379	
2023	169	
2024	189	
2025	82	
2026	86	
2027	47	

EXHIBIT 21

Fennec Pharmaceuticals Inc.

Subsidiaries

Oxiquant, Inc., a Delaware corporation

Fennec Pharmaceuticals, Inc., a Delaware corporation

Cadherin Biomedical Inc., a Canadian corporation

Fennec Pharmaceuticals (EU) Limited, an Irish Private Company Limited by Shares

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (file no. 333-221091), S-8 (on file no. 333-232353), S-3 (file no. 333-221093) and S-3 (file no. 333-219884) of Fennec Pharmaceuticals Inc. (the "Company") of our report dated February 14, 2020 relating to the consolidated financial statements as of December 31, 2019, which appear in the Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ HASKELL & WHITE LLP

HASKELL & WHITE LLP

Irvine, California
February 14, 2020

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Exhibit 31.1

FENNEC PHARMACEUTICALS INC
CERTIFICATION

I, Rostislav Raykov, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2019 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: February 14, 2020

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

Exhibit 31.2

FENNEC PHARMACEUTICALS INC.
CERTIFICATION

I, Robert Andrade, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2019 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: February 14, 2020

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, 2019 (the "Report"), each of the undersigned, Rostislav Raykov, Chief Executive Officer of the Company, and Robert Andrade, Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2020

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

Date: February 14, 2020

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

Exhibit 99.1

FENNEC PROVIDES BUSINESS UPDATE AND ANNOUNCES FISCAL YEAR 2019 FINANCIAL RESULTS

NDA (New Drug Application) and Marketing Authorization Application (MAA) completed in February 2020

Commercial readiness activities in U.S. underway for potential launch of PEDMARK™, if approved, in the second half of 2020

Solid financial position with $13.7 million and no debt and the option to access $12.5 million in debt financing upon NDA approval of PEDMARK

Research Triangle Park, NC, Feb. 14, 2020 **–**Fennec Pharmaceuticals Inc. (Nasdaq: FENC; TSX: FRX), a specialty pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate (STS)) for the prevention of platinum-induced ototoxicity in pediatric patients, today reported its business update and financial results for the fiscal year ended December 31, 2019.

"Fennec made great progress in 2019 preparing for some important milestones in 2020 including the recent announcement of regulatory submissions in both the U.S. and EU for PEDMARK" said Rosty Raykov, chief executive officer of Fennec. "During the year we also made solid progress in preparing for the potential launch of PEDMARK including the hiring of a chief commercial officer and the preparation and execution of our commercial readiness plan. We look forward to a number of significant milestones throughout 2020. If PEDMARK is granted a Priority Review, the Prescription Drug User Fee Act (PDUFA) action date is expected in the third quarter of 2020."

Financial Results for the Fourth Quarter 2019

- **Cash Position -** Cash and cash equivalents were $13.7 million as of December 31, 2019. The reduction in cash balance over the fiscal year is the result of cash used for operating activities including regulatory expenses associated with the regulatory submissions of PEDMARK and expenses associated with commercial launch preparation.
- **Research and Development (R&D) Expenses** – R&D expenses were $1.2 million and $5.6 million, respectively, for the fourth quarter and year ended December 31, 2019, compared to $1.7 million and $5.0 million for the same period in 2018. The Company completed a significant part of the activities needed for regulatory approval of PEDMARK during the fourth quarter of 2019.
- **General and Administrative (G&A) Expenses –** G&A expenses were $2.5 million and $7.4 million, respectively, for the fourth quarter and year ended December 31, 2019, compared to $1.4 million and $5.4 million, respectively for the same periods in 2018. Fourth quarter increase in G&A was largely attributable to the commercialization efforts as the Company prepares to bring PEDMARK, if approved, to market in the second half of 2020. An additional increase in G&A expenses is attributed to a small rise in compensation to officers, directors and key contract employees in fiscal 2019 as compared to fiscal 2018. Shareholders passed a motion to increase the duration of all outstanding option contracts to a total of 10 years in 2019. This added $1.3 million in G&A in non-cash compensation over the prior year. Sales and marketing expenses increased by $0.4 million over the prior year as the Company began to focus efforts to commercialize PEDMARK. The company incurred approximately $0.25 million in additional administrative expenses as it added positions to the commercial team including the addition of a Chief Commercial Officer.
- **Net Loss -**Net losses for the fourth quarter and year ended December 31, 2019 of $3.6 million ($0.18 per share) and $12.8 million ($0.64 per share), respectively, compared to $3.0 million ($0.15 per share) and $9.9 million ($0.52 per share), respectively, for the same periods in 2018.
- **Financial Guidance -** The Company believes its cash and cash equivalents on hand as of December 31, 2019, along with the $12.5 million loan facility available upon FDA approval of PEDMARK™ will be sufficient to fund the Company's planned commercial launch of PEDMARK™ in the second half of 2020.

Financial Update

The selected financial data presented below is derived from our unaudited condensed consolidated financial statements which were prepared in accordance with U.S. generally accepted accounting principles. The complete audited condensed consolidated financial statements for the period ended December 31, 2019 and management's discussion and analysis of financial condition and results of operations will be available via www.sec.gov and www.sedar.com . All values are presented in thousands unless otherwise noted.

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

	Three Months Ended		Twelve Months Ended	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	1,172	1,723	5,607	5,008
General and administrative	2,481	1,382	7,402	5,401
Loss from operations	(3,653)	(3,105)	(13,009)	(10,409)
Other (expense)/income				
Unrealized gain/(loss) on derivatives	-	-	-	167
Amortization expense	(18)	-	(64)	-
Other loss	(8)	6	(17)	6
Net interest income	69	115	315	348
Total other (expense)/income, net	43	121	234	521
Net income/(loss)	$ (3,610)	$ (2,984)	$ (12,775)	$ (9,888)
Basic net income/(loss) per common share	$ (0.18)	$ (0.15)	$ (0.64)	$ (0.52)
Diluted net income/(loss) per common share	$ (0.18)	$ (0.15)	$ (0.64)	$ (0.52)

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

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 13,650	$ 22,781
Other current assets	234	169
Non-current assets, net	262	-
Total Assets	$ 14,146	$ 22,950
Liabilities and stockholders' equity		
Current liabilities	$ 2,271	$ 1,637
Total stockholders' equity	11,875	21,313
Total liabilities and stockholders' equity	$ 14,146	$ 22,950

Working Capital	Fiscal Year Ended	
Selected Asset and Liability Data:	December 31, 2019	December 31, 2018
(U.S. Dollars in thousands)		
Cash and cash equivalents	$ 13,650	$ 22,781
Other current assets	234	169
Current liabilities excluding derivative liability	(2,271)	(1,637)
Working capital	$ 11,613	$ 21,313
Selected Equity:		
Common stock & APIC	$ 154,663	$ 151,326
Accumulated deficit	(144,031)	(131,256)
Stockholders' equity	11,875	21,313

Forward looking statements
Except for historical information described in this press release, all other statements are forward-looking. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such risks that regulatory and guideline developments may change, scientific data 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, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2019. Fennec Pharmaceuticals, Inc. 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.

About PEDMARK™ (Sodium Thiosulfate (STS))

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

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

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

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc., is a specialty pharmaceutical company focused on the development of PEDMARK™ for the prevention of platinum-induced ototoxicity in pediatric patients. PEDMARK received Breakthrough Therapy and Fast Track Designation by the FDA in March 2018. Further, PEDMARK has received Orphan Drug Designation in the U.S. for this setting. Fennec has a license agreement with Oregon Health and Science University (OHSU) for exclusive worldwide license rights to intellectual property directed to STS and its use for chemoprotection, including the prevention of ototoxicity induced by platinum chemotherapy, in humans. For more information, please visit www.fennecpharma.com.

For further information, please contact:

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