Filed Pursuant to Rule 424(b)(5)
Registration Statement No. 333-221093

SUBJECT TO COMPLETION, DATED APRIL 29, 2020

PRELIMINARY PROSPECTUS SUPPLEMENT
(To the Prospectus dated November 3, 2017)

Shares

FENNEC PHARMACEUTICALS INC.

Common Shares

We are offering of our common shares, no par value per share, pursuant to this prospectus supplement and the accompanying prospectus.

Our common shares are listed on The Nasdaq Capital Market under the symbol "FENC" and on the Toronto Stock Exchange under the symbol "FRX." On April 28, 2020, the last reported sale price of our common shares on The Nasdaq Capital Market was $7.01 per share.

Investing in our securities involves a high degree of risk. You should carefully review and consider the risks and uncertainties described under the heading "Risk Factors" beginning on page S-3 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discount (1)	$	$
Proceeds, before expenses, to us	$	$

(1) See the section of this prospectus supplement entitled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted a 30-day option to the underwriters to purchase up to additional common shares.

The underwriters expect to deliver the shares offered hereby against payment therefor on or about April , 2020.

Sole Book-Running Manager

Cantor

Co-Manager

Wedbush PacGrow

April , 2020

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Prospectus Supplement

Prospectus

ABOUT THIS PROSPECTUS SUPPLEMENT

This document contains two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated November 3, 2017, including the documents incorporated by reference therein, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission (the "SEC") before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date (for example, a document incorporated by reference in the accompanying prospectus), the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus we have authorized for use in connection with this offering. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference."

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants speak only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

All references in this prospectus supplement and the accompanying prospectus to "Fennec," the "Company," "we," "us," "our," or similar references refer to Fennec Pharmaceuticals Inc. and its subsidiaries, except where the context otherwise requires or as otherwise indicated.

We are offering to sell, and are seeking offers to buy, the shares only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the shares in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of the shares and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents the Company has filed with the SEC that are incorporated by reference in this prospectus supplement or the accompanying prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements may concern possible or anticipated future results of operations or business developments. These statements are based on management's current expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "may", "should", variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product development, product potential, regulatory environment, sales and marketing strategies, capital resources, operating performance, or the closing of this offering. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed under "Risk Factors" below, as well as any amendments to such risk factors reflected in our subsequent filings with the SEC. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the use of our existing capital resources and any proceeds we may receive from the sale of common shares offered under this prospectus supplement;
- our efforts to pursue collaborations with other companies and third parties;
- the timing and success of our clinical trials;
- our ability to enroll patients in our clinical trials at the pace that we project;
- the impact from the recent coronavirus outbreak;
- whether the results of our trials will be sufficient to support domestic or foreign regulatory approvals for our product candidate;
- our ability to obtain and maintain regulatory approval of our product candidate;
- the benefits of the use of our product candidate;
- our ability to successfully commercialize our product candidate if approved;
- the rate and degree of market acceptance of our product candidate;
- our ability to maintain, or recognize the anticipated benefits of, orphan drug designation for our product candidate;
- our ability to protect our intellectual property;
- our corporate and development strategies;
- our expected results of operations;
- our anticipated levels of expenditures;
- the nature and scope of potential markets for our product candidate; and
- our ability to attract and retain key employees.

Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made, and the Company assumes no responsibility to update any forward-looking statements except as required by law.

This prospectus supplement contains estimates, projections and other statistical data made by independent parties and by us relating to market size and growth, the incidence of certain medical conditions

and other industry data. These data, to the extent they contain estimates or projections, involve a number of subjective assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. While we believe that the data from these industry publications and other reports are generally reliable, we have not independently verified the accuracy or completeness of such data. These and other factors could cause results to differ materially from those expressed in these publications and reports.

We may from time to time provide estimates of the potential United States and foreign market for our product candidate. These estimates are based on a number of factors, including our expectation as to the number of patients with a certain medical condition that would potentially benefit from our product candidate. While we have determined these estimates based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See “Risk Factors” beginning on page S-3 of this prospectus supplement. It is possible that the ultimate market for our product candidate will differ significantly from our expectations due to these or other factors and, therefore, investors should not place undue reliance on such estimates.

SUMMARY

This summary is not complete and does not contain all the information that you should consider before investing in our common shares. Before making an investment decision, you should carefully read the entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein, including the risk factors described in "Risk Factors" beginning on page S- 3 of this prospectus supplement, as well as the financial statements and related notes and the other information incorporated by reference herein.

Company Overview

We are a biopharmaceutical company focused on the development of PEDMARK ™ (a unique formulation of Sodium Thiosulfate ("STS")) for the prevention of platinum-induced ototoxicity in pediatric cancer patients.

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 from operations of approximately $12.8 million for the twelve months ended December 31, 2019, and net loss from operations of approximately $9.9 million for the twelve months ended December 31, 2018. As of December 31, 2019, our accumulated deficit was approximately $144.0 million.

We are incorporated under the Business Corporations Act (British Columbia, Canada). 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 principal executive offices are located at PO BOX 13628, 68 TW Alexander Drive, Research Triangle Park, NC 27709. Our telephone number is (919) 636-4530. Our website is www.fennecpharma.com. Information contained in our website does not constitute part of this prospectus supplement.

THE OFFERING

Common shares offered by us	common shares.
Underwriters' option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional common shares from us at the public offering price, less the underwriting discount.
Common shares to be outstanding immediately after this offering	common shares (common shares if the underwriters' option is exercised in full).
Use of Proceeds	We intend to use the net proceeds of this offering for obtaining regulatory approvals, the potential launch of PEDMARK ™, and working capital and general corporate purposes. Our management will retain broad discretion over the allocation of the net proceeds from the sale of the common shares. See "Use of Proceeds" on page S-39 of this prospectus supplement for more information.
Risk Factors	Before purchasing our common shares, you should carefully consider the risk factors described in "Risk Factors" beginning on page S-3 of this prospectus supplement.
Exchange Listing	Our common shares are listed on The Nasdaq Capital Market under the symbol "FENC" and on the Toronto Stock Exchange under the symbol "FRX." On April 28, 2020, the last reported sale price of our common shares on The Nasdaq Capital Market was $7.01 per share.

The information set forth above is based on 19,895,830 common shares issued and outstanding on April 28, 2020 and excludes as of that date the following:

- 3,088,235 common shares issuable upon the exercise of outstanding options having a weighted average exercise price of $3.56 per share (Canadian denominated exercise prices converted using the April 21, 2020 exchange rate of 0.70978 CAD/USD);
- 39,130 common shares issuable upon the exercise of outstanding warrants having an exercise price of $6.80 per share; and
- 1,885,723 additional common shares reserved for issuance under our stock option plan.

Unless otherwise indicated, all information in this prospectus supplement assumes no exercise of the outstanding options or the warrants described above and no exercise by the underwriters of their option to purchase additional shares.

RISK FACTORS

An investment in our common shares involves a high degree of risk. Before deciding whether to invest in our common shares, you should consider carefully the risk factors described below, in conjunction with this entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement. In particular, you should carefully consider and evaluate the risks and uncertainties described below. If any of these risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the value of our common shares could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only risks facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business, operations or prospects and could cause the trading price of our common shares to decline, resulting in a loss of all or part of your investment.

Risks Related to Our Business

Our business and operations may be materially and adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States and Europe. In March 2020, the World Health Organization declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies. If the outbreak continues to spread, it may affect our operations and those of third parties on which we rely in a number of ways, including causing disruptions in the supply of our product candidate, the pending regulatory approval process and the conduct of current and planned preclinical and clinical studies. We may need to limit operations or implement limitations and may experience limitations in employee resources. There are risks that the coronavirus may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly. The extent to which the coronavirus impacts our results will depend on future developments, including, without limitation, new information that may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, all of which are highly uncertain and cannot be predicted.

Additionally, while the duration of and the potential economic impact caused by the coronavirus pandemic are difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to complete our regulatory submissions and clinical studies on a timely basis, or at all. For instance, our regulatory submissions may be temporarily delayed or paused, and the operations of our contracted third parties may be significantly delayed as well. The ultimate impact of the coronavirus pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or preclinical and clinical trial activities or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

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

A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the recent novel coronavirus outbreak), trade wars, political unrest or other events, could disrupt our business or operations or those of our manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. For example, many states recently ordered most businesses closed, mandating work-from-home arrangements where feasible, in response to the coronavirus pandemic. These limitations could negatively affect our business operations and continuity, and could negatively impact our development timelines and ability to timely perform basic business functions, including, without limitation, making SEC filings and preparing financial reports. If our operations or those of third parties with whom we conduct business are impaired or

curtailed as a result of these events, the development and commercialization of our products and product candidate could be impaired or halted, which could have a material adverse impact on 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 New Drug Application (“NDA”), with the U.S. Food and Drug Administration (“FDA”). 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.

We believe that the proceeds of this offering, our existing cash and cash equivalents (approximately $13.7 million as of December 31, 2019), and the $12.5 million debt facility announced in February 2019 (which will be funded if we receive FDA approval of PEDMARK ™ by no later than September 30, 2020) 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.

Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. If these conditions in the capital markets continue for an extended period of time, it may

impact our ability to raise capital. If we fail to obtain additional funding when needed, we may ultimately be unable to continue to develop and potentially commercialize our product candidate, and we may be forced to scale back or terminate our operations or seek to merge with or be acquired by another company.

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 Oregon Health & Science University ("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. Further, the collaborators on which we rely may be impacted by the coronavirus outbreak. 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 agreements on acceptable terms with prospective clinical trial sites, the impact of the coronavirus pandemic 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:

- we suffer a lack of sufficient funding;
- new information that may emerge concerning the severity of the coronavirus and the actions to contain or treat the coronavirus;
- PEDMARK ™ is determined to be ineffective;
- patients experience severe side effects during treatment with PEDMARK ™ ;
- qualified patients not enrolling in PEDMARK ™ studies at the rate expected;
- supplies of PEDMARK ™ not being sufficient to treat the patients in the studies; or
- our decision to modify PEDMARK ™ during testing.

If regulatory approval of PEDMARK ™ is granted, it will be limited to those indications for which it 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 PEDMARK ™ .

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 capital for the development of PEDMARK ™.

Any inability on our part to manage effectively the deployment of our existing capital or proceeds from this offering could limit our ability to successfully develop PEDMARK ™.

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.

PEDMARK is currently protected by a “method of use” patent owned by Fennec which expires in January 2038 and captures the use of PEDMARK to reduce the ototoxic effects of cisplatin in pediatric patients, particularly in the age group of five years or younger. Further, PEDMARK is 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 PEDMARK 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 PEDMARK 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.

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.

PEDMARK 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. While we believe that we currently have sufficient supply of PEDMARK for our planned commercial launch, some of our other product candidates or the materials contained therein, may come from facilities in areas impacted by the coronavirus, which may result in delays or shortages due to ongoing efforts to address the outbreak. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to successfully launch PEDMARK, or if we obtain regulatory approval, to commercialize it.

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(“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 (“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 an 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 (“cGMP”), requirements. The FDA and the Competent Authorities of the Member States of the European Economic Area (“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 current good clinical practice (“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. Further, the coronavirus pandemic has led to significant uncertainty due to stay-at-home orders from several states. If the uncertainty related to the coronavirus continues for an extended period of time, it may impact the activities of the FDA and 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 compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as 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 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 good clinical practice standards ("GCPs") 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 (“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 (“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 (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 candidate, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidate if it obtains 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 candidate.

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 candidate are smaller than we believe they are, then our revenues may be adversely affected, and our business may suffer.

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

Coverage and reimbursement may be limited or unavailable in certain market segments for our product 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 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 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 maintain the orphan drug designation for PEDMARK ™, 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 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 candidate, 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.

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

Efforts to reduce product pricing and health care reimbursement and changes to government policies could negatively affect the 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 April 28, 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 (the date our common shares were initially listed on The Nasdaq Capital Market) to April 28, 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;
- the impact of the coronavirus pandemic;
- 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 April 28, 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 Avoro owns approximately 1.1 million shares, or approximately 5.6% of our issued and outstanding common shares. Southpoint Capital, Essetifin SpA, Avoro, 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 April 28, 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 April 28, 2020, there were approximately 3.1 million common shares issuable upon the exercise of outstanding stock options, of which options to purchase approximately 0.65 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 2.4 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 1.8 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 candidate, 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 available cash, including cash from proceeds of this offering.

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 (including cash from the proceeds of this offering) 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 ("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 prospectus supplement captioned "Material United States 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 will endeavor 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, but there can be no assurance that we will timely provide such required information. 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 prospectus supplement entitled "Material United States Federal Income Tax Considerations — Tax Consequences if We Are a Passive Foreign Investment Company." This paragraph is qualified in its entirety by the discussion below under the heading "Material United States 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.

Risks Related to this Offering

As a new investor, you will incur substantial dilution as a result of this offering and future equity issuances, and as a result, our share price could decline.

The offering price of this offering is substantially higher than the net tangible book value per share of our outstanding common shares. As a result, based on the net tangible book value of our common shares as of December 31, 2019, an investor purchasing common shares in this offering will incur immediate and substantial dilution of $ per share. See the section entitled "Dilution" on page S- 42 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common shares in this offering

Subject to market conditions and other factors, we may pursue raising additional funds in the future, as we continue to build our business. In future years, we will likely need to raise additional funding to finance our operations and to fund clinical trials, regulatory submissions and the development, manufacture and marketing of other products under development and new product opportunities. Accordingly, we may conduct future offerings of equity or debt securities. The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional shares issued in connection with acquisitions, will also result in dilution to investors. In addition, the market price of our common shares could fall as a result of resales of any of these common shares.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We may in the future issue additional common shares or other securities convertible into or exchangeable for our common shares. We cannot assure you that we will be able to sell common shares or other securities in any other offering or other transactions at a price per share that is equal to or greater than the price per share paid by investors in this offering. The price per share at which we sell additional common shares or other securities convertible into or exchangeable for our common shares in future transactions may be higher or lower than the price per share in this offering.

In addition, we have a substantial number of stock options and warrants outstanding. To the extent that outstanding stock options and warrants may be exercised or other shares issued, investors purchasing our common shares in this offering may experience further dilution.

We will have broad discretion in how we use the proceeds from this offering, and our use of the offering proceeds may not yield a favorable return on your investment.

We currently anticipate that the net proceeds from this offering will be used primarily for obtaining regulatory approvals, the potential launch of PEDMARK ™, and working capital and general corporate purposes. Pending the application of the net proceeds, we intend to invest the net proceeds in investment-grade, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree, and the proceeds may not be invested in a manner that yields a favorable or any return. Our failure to use these funds effectively could have a material adverse effect on our business.

USE OF PROCEEDS

We estimate that the net proceeds of this offering, after deducting the underwriting discount and estimated offering expenses payable by us, will be approximately $ million ($ million if the underwriters exercise in full their option to purchase additional shares).

We intend to use the net proceeds from this offering for obtaining regulatory approvals, the potential launch of PEDMARK ™, and working capital and general corporate purposes. Our management will retain broad discretion over the allocation of the net proceeds from the sale of the common shares. We have no current understandings, agreements or commitments for any material acquisitions.

Therefore, investors in our common shares will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, our cash needs, the rate of adoption of our products by the medical community and efficiency of our product development. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

Pending the application of the net proceeds, we intend to invest the net proceeds in money market accounts and/or investment-grade, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree, and the proceeds may not be invested in a manner that yields a favorable or any return.

DIVIDEND POLICY

We currently intend to retain earnings, if any, to finance the growth and development of our business, and do not expect to pay any cash dividends to our shareholders in the foreseeable future.

CAPITALIZATION

The following table describes our capitalization as of December 31, 2019:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of common shares in this offering at the public offering price of $ per share, after deducting the underwriting discount and estimated offering expenses payable by us.

You should read this capitalization table together with our consolidated financial statements and the related notes and other financial information incorporated by reference in this prospectus supplement and the accompanying prospectus and the "Use of Proceeds" section.

	As of December 31, 2019	
	Actual	As Adjusted
	(in thousands, except share and per share data)	
Assets		
Current assets		
Cash and cash equivalents	$ 13,650	$
Prepaid expenses	226	226
Other current assets	8	8
	13,884	
Non-current assets		
Deferred issuance costs	$ 326	$ 326
Deferred issuance costs (amortization)	(64)	(64)
	262	262
Total assets	$ 14,146	$
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 1,612	$ 1,612
Accrued liabilities	659	659
Total current liabilities	2,271	$ 2,271
Total liabilities	$ 2,271	$ 2,271
Shareholders' equity		
Common stock, no par value; unlimited shares authorized; 19,895,830 shares issued and outstanding	$ 106,392	$
Additional paid-in capital	48,271	
Accumulated deficit	(144,031)	
Accumulated other comprehensive income	1,243	
Total shareholders' equity	$ 11,875	$
Total liabilities and shareholders' equity	$ 14,146	$

Information in the above table is based on 19,895,830 common shares issued and outstanding on December 31, 2019 and excludes as of that date the following:

- 3,088,235 common shares issuable upon the exercise of outstanding options having a weighted average exercise price of $3.59 per share (Canadian denominated exercise prices converted using the December 31, 2019 exchange rate of 0.7682 CAD/USD);
- 39,130 common shares issuable upon the exercise of outstanding warrants having an exercise price of $6.80 per share; and
- 1,885,723 additional common shares reserved for issuance under our stock option plan.

DILUTION

Investors in this offering will suffer immediate and substantial dilution in the net tangible book value per share of the common shares they purchase. Our net tangible book value as of December 31, 2019 was approximately $11.9 million, or approximately $0.60 per common share. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the actual number of common shares outstanding. After giving effect to the sale of common shares in this offering at the public offering price of $ per share, and after deducting the underwriting discount and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2109 would have been approximately $ million or approximately $ per common share. This represents an immediate increase in as adjusted net tangible book value of approximately $ per share to our existing shareholders and an immediate dilution of $ per share to new investors in this offering. The following table illustrates this per share dilution:

Public offering price per common share		$
Net tangible book value per common share as of December 31, 2019	$ 0.60	
Increase in net tangible book value per common share attributable to this offering	$	
As adjusted net tangible book value per common share after this offering		$
Dilution per common share to new investors		$

If the underwriters exercise in full their option to purchase additional shares, the as adjusted net tangible book value deficit after this offering would be $ per share, representing an increase in net tangible book value of $ per share to existing shareholders and immediate dilution in net tangible book value of $ per share to purchasers in this offering.

The table and discussion above are based on 19,895,830 common shares issued and outstanding on December 31, 2019 and excludes as of that date the following:

- 3,088,235 common shares issuable upon the exercise of outstanding options having a weighted average exercise price of $3.59 per share (Canadian denominated exercise prices converted using the December 31, 2019 exchange rate of 0.7682 CAD/USD);
- 39,130 common shares issuable upon the exercise of outstanding warrants having an exercise price of $6.80 per share; and
- 1,885,723 additional common shares reserved for issuance under our stock option plan.

To the extent that any of the outstanding warrants or options are exercised, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity securities, the issuance of these securities could result in further dilution to our shareholders.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2020, between us and Cantor Fitzgerald & Co., 499 Park Avenue, New York, New York 10022, as representative of the underwriters named below (the "Representative") and the sole book-running manager of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of common shares shown opposite its name below:

Underwriter	Number of Shares
Cantor Fitzgerald & Co.	
Wedbush Securities Inc.	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the common shares if any of them are purchased. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the common shares subject to their acceptance of the common shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to certain conditions, to purchase a number of additional shares approximately proportionate to that underwriter's initial purchase commitment as indicated in the table above.

Commission and Expenses

The underwriters have advised us that they propose to offer the common shares to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per common share. The underwriters may allow a discount from the concession not in excess of $ per common share to certain brokers and dealers. After the initial offering, the Representative may change the offering price and other selling terms.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	$	$	$	$
Underwriting discounts and commissions	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to reimburse the underwriters for up to $100,000 of certain of their counsels' fees and expenses, which reimbursed fee is deemed underwriting compensation for this offering by FINRA.

Listing

Our common shares are listed on The Nasdaq Capital Market under the trading symbol "FENC" and on the Toronto Stock Exchange under the symbol "FRX."

No Sales of Similar Securities

We, our officers and our directors have agreed, subject to certain specified exceptions, not to directly or indirectly, for a period of 90 days after the date of the underwriting agreement:

(i) sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act or otherwise dispose of, any common shares, options or warrants to acquire common shares, or securities exchangeable or exercisable for or convertible into common shares currently or hereafter owned either of record or beneficially,

(ii) enter into any swap, hedge or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of common shares, or securities exchangeable or exercisable for or convertible into common shares, or

(iii) publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of the Representative.

In addition, we and each such person agrees that, without the prior written consent of the Representative, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any common shares or any security convertible into or exercisable or exchangeable for common shares.

The restrictions in the immediately preceding paragraph do not apply in certain circumstances, including:

(i) the transfer of securities as a bona fide gift;

(ii) if the locked up party is a corporation, the transfer of securities to any trust for the direct or indirect benefit of such locked up party or the immediate family of the locked up party;

(iii) if the locked up party is a corporation, partnership, limited liability company, trust or other business entity (1) transfers to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the locked up party or (2) distributions of our common shares or any security convertible into or exercisable for our common shares to limited partners, limited liability company members or stockholders of the locked up party or holders of similar equity interests in the locked up party;

(iv) if the locked up party is a trust, transfers to the beneficiary of such trust;

(v) transfers by testate succession or intestate succession;

(vi) transfers to any immediate family member or any investment fund or other entity controlled or managed by the locked up party;

(vii) transfers to a charitable organization or educational institution;

(viii) transfers to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible pursuant to (i) through (vii) above;

(ix) transfers to the Company in connection with, and only to the extent necessary to fund, the

payment of taxes due with respect to the vesting of restricted stock, restricted stock units or similar rights to purchase our common shares pursuant to our equity incentive plans described in the Company's registration statement;

(x) pursuant to any contractual arrangement described in the Company's registration statement that provides for the repurchase of the locked up party's securities by the Company in connection with the termination of the locked up party's employment or other service relationship with the Company or the locked up party's failure to meet certain conditions set out upon receipt of such securities;

(xi) transfers of securities that the locked up party may purchase in this offering;

(xii) transfers of securities acquired by the locked up party in open market transactions after completion of this offering;

(xiii) transfers in response to a bona fide third-party takeover bid made to all holders of our common shares or any other acquisition transaction whereby not less than a majority of our common shares are acquired by a third party; or

(xiv) subject to certain qualifications, transfers pursuant to an order of a court or regulatory agency.

Notwithstanding the foregoing, our lock-up agreements with our Chief Executive Officer and Chief Financial Officer (Rostislav Raykov and Robert Andrade, respectively), provide that each of them may, beginning on a date that is 31 days after the date of this prospectus supplement, sell up to 120,000 common shares solely to satisfy the payment of tax withholding obligations due as a result of the exercise of stock options held by them.

The Representative may, in its sole discretion and at any time or from time to time before the termination of the 90-day period release all or any portion of the securities subject to lock-up agreements.

Market Making, Stabilization and Other Transactions

The underwriters may make a market in the common shares as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common shares, that you will be able to sell any of the common shares held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common shares at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional common shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional common shares or purchasing common shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional common shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of our common shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the common shares. A syndicate covering transaction is the bid for or the purchase of our common shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As a result, the price of our common shares may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common shares originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common shares. The underwriters are not obligated to engage in these activities and, if commenced, may end any of these activities at any time.

Passive Market Making

The underwriters may also engage in passive market making transactions in our common shares on the Nasdaq in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of our common shares in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common shares to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters, selling group members (if any) or their affiliates. The underwriters may agree with us to allocate a specific number of our common shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may include, among other things, corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of its business, the underwriters and their respective affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Stamp Taxes

If you purchase common shares offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

NOTICE TO INVESTORS

Canada

The securities subject to this offering are not qualified for sale in Canada and may not be offered or sold in Canada, directly or indirectly, on our behalf. Purchasers of the securities subject to this offering are hereby notified that their purchase of securities subject to this offering will be deemed to constitute a representation and warranty that such investor is not a Canadian resident and is purchasing the shares with investment intent and not for the purposes of making an immediate resale in Canada.

European Economic Area

In relation to each Member State of the European Economic Area , no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the relevant competent authority in that Member State in accordance with the Prospectus Regulation, except that an offer of such securities may be made to the public in that Member State:

- to any legal entity which is a “qualified investor” as defined in the Prospectus Regulation;
- to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Regulation in that Member State and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors (as defined in the Prospectus Regulation) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the “Order”, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated or caused to be communicated. Each such person is referred to herein as a “Relevant Person”.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the “FSMA”) may only be communicated or caused to be

communicated in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply. All applicable provisions of the FSMA must be complied with in respect of anything done by any person in relation to the securities in, from or otherwise involving the United Kingdom.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

    A. shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

    - to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;
    - where no consideration is given for the transfer; or
    - where the transfer is by operation of law.

MATERIAL UNITED STATES AND CANADIAN TAX CONSEQUENCES OF THIS OFFERING

Material U.S. Federal Income Tax Considerations

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

General

Tax Consequences Not Addressed

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

Authorities

This summary is based upon the provisions of the United States Internal Revenue Code (the "Code"), the United States Treasury Regulations (whether final, temporary, or proposed) promulgated thereunder, the Convention Between Canada and the United States of America with Respect to Taxes on Income and on Capital, signed September 26, 1980, as amended (the "Canada-U.S. Tax Convention"), and administrative rulings and judicial decisions interpreting the Code and the United States Treasury Regulations, all as currently in effect, and all subject to differing interpretations or change, possibly on a retroactive basis. We have not sought, and will not seek, a ruling from the IRS regarding any matter discussed herein, and no assurance can be given that the IRS would not assert, or that a court would not sustain, a position that is different from, and contrary to, the positions taken in this summary. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation.

U.S. Holders

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

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

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

preceding year, and one-sixth of the days present in the second preceding year are counted. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

Non-U.S. Holders Not Addressed

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

Certain U.S. Holders Not Addressed

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

- are tax-exempt organizations, qualified retirement plans, individual retirement accounts, or other tax-deferred accounts;
- are financial institutions, underwriters, insurance companies, real estate investment trusts, or regulated investment companies;
- are broker-dealers, dealers, or traders in securities or currencies that elect to apply a mark-to-market accounting method;
- have a "functional currency" other than the U.S. dollar;
- own common shares as part of a straddle, hedging transaction, conversion transaction, constructive sale, or other arrangement involving more than one position;
- acquired common shares in connection with the exercise of employee stock options or otherwise as compensation for services;
- hold common shares other than as a capital asset within the meaning of section 1221 of the Code (generally, property held for investment purposes);
- are partnerships or other "pass-through" entities for U.S. federal income tax purposes (or investors in such partnerships or entities);
- own, have owned, or will own (directly, indirectly, or by attribution) 10% or more of the total combined voting power of the outstanding shares of your company;
- are U.S. expatriates who are former citizens or long-term residents of the United States;
- have been, are, or will be residents or deemed to be residents in Canada for purposes of the Income Tax Act (Canada) (the "Tax Act");
- use or hold, will use or hold, or that are or will be deemed to use or hold common shares in connection with carrying on a business in Canada;
- are persons whose common shares constitute "taxable Canadian property" under the Tax Act; or
- have a permanent establishment in Canada for the purposes of the Canada-U.S. Tax Convention.

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

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

General Rules Applicable to the Ownership and Disposition of Common Shares

The following discussion describes the general rules applicable to the ownership and disposition of the common shares but is subject in its entirety to the special rules described below under the headings entitled

"Tax Consequences if We Are a Passive Foreign Investment Company" and "Tax Consequences if We are a Controlled Foreign Corporation."

Distributions on Common Shares

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

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

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

Sale or Other Taxable Disposition of Our Common Shares

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

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

Additional Medicare Tax on Net Investment Income

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

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

Receipt of Foreign Currency

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

Foreign Tax Credit

Subject to the PFIC rules discussed below, a U.S. Holder that pays (whether directly or through withholding) Canadian income tax with respect to dividends paid on the common shares generally will be entitled, at the election of such U.S. Holder, to receive either a deduction or a credit for such Canadian income tax paid. Generally, a credit will reduce a U.S. Holder's U.S. federal income tax liability on a dollar-for-dollar basis, whereas a deduction will reduce a U.S. Holder's income that is subject to U.S. federal income tax. This election is made on a year-by-year basis and applies to all foreign taxes paid (whether directly or through withholding) by a U.S. Holder during a year.

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

Information Reporting and Backup Withholding

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

Distributions paid with respect to common shares and proceeds from a sale, exchange, or redemption of common shares made within the United States or through certain U.S.-related financial intermediaries may be subject to information reporting to the IRS and possible U.S. backup withholding (at a rate of 28%). Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct U.S. taxpayer

identification number and makes any other required certification on IRS Form W-9 or that is a corporation or other entity that is otherwise exempt from backup withholding. Each U.S. Holder should consult its own tax advisors regarding the application of the U.S. information reporting and backup withholding rules. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability, and such holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

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

Tax Consequences if We are a Passive Foreign Investment Company

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

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

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

Alternatively, a U.S. Holder may make an election which will be effective with respect to all interests in a PFIC for which a "qualified electing fund" election has been made and which is held in that year or acquired in future years. Under this election, a U.S. Holder pays the additional 3.8% tax on income inclusions resulting from the "qualified electing fund" election and on gains calculated after giving effect to related tax basis adjustments.

Tax Consequences if We are a Controlled Foreign Corporation

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

In addition to the inclusion of "Subpart F income" of a CFC in the gross income of a United States Shareholder, there may be exposure to an additional tax under the recently enacted Global Intangible Low Tax Income regime ("GILTI"). Specifically, the GILTI rules impose an annual minimum tax on U.S. Holders of their share of GILTI income generated through CFCs. This GILTI income very generally equals a CFC's income over a 10% return on the CFCs tangible depreciable trade or business assets. The GILTI tax is 10.5% (until 2026 and 13.12% for tax years after) on U.S. Holders who are C corporations, as they are entitled to a 50% deduction (37.5% after 2025) of the GILTI income as well as a reduced foreign tax credit on foreign taxes paid on the GILTI income. U.S. Holders who are individuals, estates or trusts may pay substantially more tax on GILTI income, as they are subject to ordinary tax rates (ranging from 10% to 37% plus the net investment income tax of 3.8%). Such U.S. Holders are not entitled to a deduction on GILTI income or a reduced foreign tax credit. There is, however, an election available to such U.S. Holders to mitigate the tax impact.

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

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

Material Canadian Federal Income Tax Considerations

Non-Residents of Canada

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

Disposition of Common Shares

Upon the disposition by a U.S. Holder of common shares in our Company, the U.S. Holder will not be subject to tax under the Tax Act in respect of any capital gain realized unless the common shares disposed of constitutes "taxable Canadian property" of the U.S. Holder and the U.S. Holder is not entitled to relief under an applicable tax treaty or convention. Common shares will generally not constitute "taxable Canadian property" of such U.S. Holder unless at any time in the preceding 60 months both of the following

statements were true: (a) the U.S. Holder, together with either (i) persons with whom the U.S. Holder does not deal at arm's length or (ii) partnerships in which the U.S. Holder or a person in (a) directly or indirectly hold membership interests, held shares and/or rights to acquire shares representing 25% or more of the issued shares of any class of our capital stock; and (b) more than 50% of the fair market value of our common stock was derived directly or indirectly from one or any combination of (i) real or immovable property situated in Canada, (ii) Canadian resource properties, (iii) timber resource properties, and (iv) options in respect of, or interests in, or for civil law rights in, property described in any of (i) to (iii).

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

Dividends Paid on Common Shares

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

LEGAL MATTERS

Certain legal matters in connection with the securities offered hereby will be passed upon for us by LaBarge Weinstein LLP, Ottawa, Ontario. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts, is acting as counsel to the underwriters in connection with this offering.

EXPERTS

The consolidated financial statements of Fennec Pharmaceuticals Inc. appearing in our Annual Report on Form 10-K for the year ended December 31, 2019 have been audited by Haskell & White LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference in reliance upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus are only parts of a registration statement on Form S-3 (File No. 333-221093) that we filed with the SEC under the Securities Act and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference in this prospectus supplement and the accompanying prospectus for a copy of such contract, agreement or other document.

We are a public company and file proxy statements, annual, quarterly and special reports and other information with the SEC. The registration statement, such reports and other information can be accessed electronically by means of the SEC's home page on the internet (www.sec.gov).

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports available through our website, free of charge, as soon as reasonably practicable after we file such material with, or furnish it to the SEC. Our website address is www.fennecpharma.com. We have included our website address in this prospectus supplement solely as an inactive textual reference. The information contained on, or that can be accessed through, our website is not part of this prospectus supplement.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information contained in this prospectus supplement and the accompanying prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and the accompanying prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (other than Current Reports on Form 8-K furnished under Item 2.02 or Item 7.01 and exhibits filed on such form that are related to such items) we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the prospectus supplement and until the termination of this offering:

- our Annual Report on Form 10-K for the year ended December 31, 2019;
- our Current Reports on Form 8-K filed with the SEC on February 11, 2020, February 28, 2020, March 5, 2020 and April 13, 2020; and
- the description of our common shares set forth in our registration statement on Form 8-A filed with the SEC on September 11, 2017, including any amendments or reports filed for the purpose of updating such description.

To receive a free copy of any of the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, other than any exhibits, unless the exhibits are specifically incorporated by reference into this prospectus, call or write us at the following address and telephone number:

Fennec Pharmaceuticals Inc.
PO Box 13628
68 TW Alexander Drive
Research Triangle Park, North Carolina 27709
(919) 636-4530

$90,000,000
Common stock

Fennec Pharmaceuticals Inc. may offer from time to time up to an aggregate of $90,000,000 of common stock in one or more offerings.

This prospectus describes the general manner in which these securities may be offered and sold. If necessary, the specific manner in which these securities may be offered and sold will be described in a supplement to this prospectus.

Our common stock is listed on The Nasdaq Capital Market ("NASDAQ") under the symbol "FENC" and on the Toranto Stock Exchange ("TSX") under the symbol "FRX.". The last reported sale price of the shares of our common stock on NASDAQ on October 5, 2017, was $11.74 per share. The aggregate market value of our common stock held by non-affiliates pursuant to General Instruction I.B.6 of Form S-3 is $104,347,526.70, which was calculated based on 8,888,205 shares of our common stock outstanding held by non-affiliates and at a price of $11.74 per share, which was the closing price of our common stock on October 5, 2017. As of the date of this prospectus, we have not sold any common stock pursuant to General Instruction I.B.6 to Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus.

Investing in our securities involves risks. You should carefully consider the risks described under "Risk Factors" in Item 1A of our most recent Annual Report on Form 10-K and Item 1A of any subsequently filed Quarterly Reports on Form 10-Q (which documents are incorporated by reference herein), as well as the other information contained or incorporated by reference in this prospectus or in any prospectus supplement hereto before making a decision to invest in our securities. See "Where You Can Find More Information" below.

Neither the Securities and Exchange Commission nor any state securities commission or other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 3, 2017

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You should rely only on the information contained or incorporated by reference in this prospectus or any supplement to this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer to sell or seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus or any supplement to this prospectus is accurate as of any date other than the date on the front cover of those documents. You should read all information supplementing this prospectus.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a "shelf" registration process. Under the shelf registration process, we may offer from time to time up to an aggregate of $90,000,000 of common stock in one or more offerings.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you should rely on the information in the prospectus supplement. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to a particular offering. For the securities being sold, the prospectus supplement will include the names of the underwriters, dealers or agents, if any, their compensation, the terms of the offering, and the net proceeds to the Company. The prospectus supplement may also contain additional information about certain United States federal income tax considerations relating to the securities covered by the prospectus supplement. You should read both this prospectus and any prospectus supplement, together with additional information described under the heading "Where You Can Find More Information."

Unless the context suggests otherwise, references in this prospectus to "Fennec Pharmaceuticals," the "Company," "we," "us" and "our" refer to Fennec Pharmaceuticals Inc. and its consolidated subsidiaries.

FENNEC PHARMACEUTICALS INC.

This is only a summary and may not contain all the information that is important to you. You should carefully read both this prospectus and any accompanying prospectus supplement and any other offering materials, together with the additional information described under the heading "Where You Can Find More Information". Unless otherwise noted, the terms "Fennec Pharmaceuticals", "the Company," "we," "us," and "our" refer to Fennec Pharmaceuticals Inc. and its wholly-owned subsidiaries.

We incorporated under the laws of Canada in September 1996. On August 25, 2011, we continued from the laws of Canada under the *Canada Business Corporations Act* (the "CBCA") to the laws of British Columbia in accordance with Section 302 of the *Business Corporations Act (British Columbia)* (the "Continuance").

Our principal executive offices are located at PO BOX 13628, 68 TW Alexander Drive, Research Triangle Park, NC 27709. Our telephone number is (919) 636-4530. Our website is www.fennecpharma.com. Information contained in our website does not constitute part of this prospectus.

We are a biopharmaceutical company focused on the development of Sodium Thiosulfate ("STS") for the prevention of platinum-induced ototoxicity in pediatric cancer patients.

FORWARD LOOKING STATEMENTS

This prospectus contains or incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which reflect our current views with respect to, among other things, our operations and financial performance. In some cases, you can identify these forward-looking statements by the use of words such as "outlook", "believes", "expects", "potential", "continues", "may", "will", "should", "seeks", "approximately", "predicts", "intends", "plans", "estimates", "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. These forward-looking statements are not historical facts and are based on current expectations, estimates and projections about Fennec Pharmaceuticals's industry, management's beliefs and certain assumptions made by management, many of which, by their nature, are inherently uncertain and beyond our control.

Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. All statements other than statements of historical fact are forward-looking statements and are based on various underlying assumptions and expectations and are subject to known and unknown risks, uncertainties and assumptions, and may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. We believe these factors include, but are not limited to, those described under "Risk Factors" in Item 1A of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 29, 2017, and Item 1A of any subsequently filed Quarterly Reports on Form 10-Q, as such factors may be updated from time to time in our periodic filings with the SEC (which documents are incorporated by reference herein), as well as the other information contained or incorporated by reference in this prospectus or in any prospectus supplement hereto. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included or incorporated by reference in this prospectus or in any prospectus supplement hereto. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy any documents filed by us at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. Our filings with the SEC are also available to the public through the SEC's Internet site at *http://www.sec.gov* . We make available free of charge on our website (http://www.Fennecpharma.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the SEC.

We have filed a registration statement on Form S-3 with the SEC relating to the securities covered by this prospectus. This prospectus is a part of the registration statement and does not contain all of the information in the registration statement. Whenever a reference is made in this prospectus to a contract or other document of ours, please be aware that the reference is only a summary and that you should refer to the exhibits that are part of the registration statement for a copy of the contract or other document. You may review a copy of the registration statement at the SEC's public reference room in Washington, D.C., as well as through the SEC's Internet site.

The SEC's rules allow us to "incorporate by reference" information into this prospectus. This means that we can disclose important information to you by referring you to another document. Any information referred to in this way is considered part of this prospectus from the date we file that document. Any reports filed by us with the SEC after the date of the initial registration statement and prior to effectiveness of the registration statement and any reports filed by us with the SEC after the date of this prospectus and before the date that the offerings of the securities by means of this prospectus are terminated will automatically update and, where applicable, supersede any information contained in this prospectus or incorporated by reference in this prospectus.

We incorporate by reference into this prospectus the following documents or information filed with the SEC:

(1) Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 29, 2017 (File No. 001-32295);

(2) Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017 filed with the Commission on May 12, 2017 and August 14, 2017, respectively (File No. 001-32295);

(3) Current Reports on Form 8-K as filed with the SEC on May 17, 2017, June 9, 2017, June 29, 2017, September 13, 2017, September 29, 2017 and October 16, 2017 (other than any reports or portions thereof that are furnished under Item 2.02 or Item 7.01 and any exhibits included with such Items) (File No. 001-32295);

(4) the description of our capital stock contained in our Registration Statement on Form 8-A filed with the Commission on September 11, 2017 (File No. 001-32295), including any amendment or report filed for the purpose of updating such description; and

(5) All documents filed by us under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement and prior to effectiveness of the registration statement and after the date of this prospectus and before the termination of the offerings to which this prospectus relates.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all documents referred to above which have been or may be incorporated by reference into this prospectus, excluding exhibits to those documents unless they are specifically incorporated by reference into those documents. You can request those documents from the Corporate Secretary, Fennec Pharmaceuticals Inc., at 68 TW Alexander Drive, Research Triangle Park, NC 27709. You may also contact the Corporate Secretary at (919) 636-4530.

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, we intend to use the net proceeds from our sale of securities pursuant to this prospectus to pursue the research and development of STS, as well as working capital and general corporate purposes, including to fund our ongoing research and development and product initiatives. We have not allocated the proceeds to these purposes as of the date of this prospectus. Allocation of the proceeds of a particular series of securities, or the principal reasons for the offering, if no allocation has been made, will be described in the applicable prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock does not purport to be complete and is subject to and qualified in its entirety by reference to our Articles of Incorporation and our Bylaws, each of which may be further amended from time to time and both of which are incorporated herein by reference.

General

As of October [ ], 2017 our authorized capital stock consists of unlimited shares of common stock, no par value per share. As of September 30, 2017, 15,856,738 shares of common stock were issued and outstanding.

Common Stock

Pursuant to our Notice of Articles and Articles, as amended, we are authorized to issue an unlimited number of common shares, no par value. Each holder of a Share is entitled to one vote for each common share held on all matters submitted to a vote of shareholders. We have not provided for cumulative voting for the election of directors in our Notice of Articles or Articles, as amended. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election. The holders of outstanding our common shares are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time.

Holders of common shares have no preemptive subscription, redemption or conversion rights or other subscription rights. Upon our liquidation, dissolution or winding-up, the holders of common shares are entitled to share in all assets remaining after payment of all liabilities. The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future. Each outstanding common share is, and all common shares to be issued in this offering, when they are paid for, will be fully paid and non-assessable.

Computershare is the transfer agent for our common stock.

Our common stock is listed on the NASDAQ Capital Market under the symbol “FENC”.

Exchange Controls, Restrictions on Voting or Ownership

There is currently no law, governmental decree or regulation in Canada that restricts the export or import of capital, or which would affect the remittance of dividends, interest or other payments by us to a non-resident holder of our common shares, other than applicable tax requirements.

There is currently no limitation imposed by the laws of Canada or by our Notice of Articles or Articles on the right of a non-resident to hold or vote our common shares, other than those imposed by the *Investment Canada Act* and the *Competition Act* (Canada). These acts will generally not apply except where control of an existing Canadian business or company, which has Canadian assets or revenue over a certain threshold, is acquired and will not apply to trading generally of securities listed on a stock exchange. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to be of net benefit to Canada.

Shareholders’ Rights Plan

The Company adopted a shareholder rights plan agreement (the “Rights Plan”) on June 27, 2017. The Rights Plan was adopted to ensure, to the extent possible, that all of our shareholders are treated fairly and

equally in connection with any take-over bid or other acquisition of control. Generally stated, the Rights Plan is designed to address this purpose by requiring any potential transaction that will result in a person (an "Acquiring Person") owning, in the aggregate, 20% or more of our outstanding common stock (inclusive of any shares of common stock held by the Acquirer, its associates and affiliates, and any person acting jointly or in concert with any of them (collectively, the "Acquirer Group")) to be structured as a formal take-over bid that satisfies certain minimum requirements relating primarily to the manner in which the bid must be made, the minimum number of days the bid must remain open, and the minimum number of shares that must be acquired under the bid. Non-compliant transactions may, through the operation of the Rights Plan and the rights issued thereunder, result in the Acquirer Group's common stock position in us being substantially diluted. Consequentially, the Rights Plan incentivizes the Acquirer to structure its proposed transaction in a manner that complies with the minimum requirements prescribed by the Rights Plan, thereby helping fulfill the purpose of the Rights Plan. One right (a "Right") is issued and attached to each share of common stock. This includes all common stock issued as of theeffective date of the Rights Plan and all shares of common stock issued after the effective date of the Rights Plan but prior to the eighth trading day after the earlier of public announcement of of a take-over bid (other than a take over bid that is a permitted bid or a competing permitted bid, as the case may be, under the Rights Plan) or the date upon which a permitted bid or competing permitted bid under the Rights Plan ceases to be such, or such later date as may be determined by our board of directors.

CERTAIN ERISA MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the offered securities may, subject to certain legal restrictions, be held by (i) an "employee benefit plan" (as defined in Section 3(3) of the Employee Retirement Security Act of 1974, as amended ("ERISA")) that is subject to Title I of ERISA, (ii) a "plan" as defined in, and subject to, Section 4975 of the Code or (iii) a "benefit plan investor" within the meaning of Section 3(42) of ERISA. A fiduciary of any such employee benefit plan, plan, or benefit plan investor must determine that the purchase, holding and disposition of an interest in such offered security is consistent with its fiduciary duties and will not constitute or result in a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code.

PLAN OF DISTRIBUTION

We may from time to time offer and sell some or all of the securities covered by this prospectus. Registration of securities covered by this prospectus does not mean, however, that those securities necessarily will be offered or sold.

The securities covered by this prospectus may be sold from time to time, at market prices prevailing at the time of sale, at prices related to market prices, at a fixed price or prices subject to change or at negotiated prices, by a variety of methods including the following:

- on the NASDAQ Capital Market (including through at the market offerings);
- on the Toronto Stock Exchange (including through at the market offerings);
- in the over-the-counter market;
- in privately negotiated transactions;
- through broker/dealers, who may act as agents or principals;
- through one or more underwriters on a firm commitment or best-efforts basis;
- in a block trade in which a broker/dealer will attempt to sell a block of securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through put or call option transactions relating to the securities;
- directly to one or more purchasers;
- through agents; or
- in any combination of the above.

In effecting sales, brokers or dealers engaged by us may arrange for other brokers or dealers to participate. Broker/dealer transactions may include:

- purchases of securities by a broker/dealer as principal and resales of the securities by the broker/dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions; or
- transactions in which the broker/dealer solicits purchasers on a best efforts basis.

We have not entered into any agreements, understandings or arrangements with any underwriters or broker/dealers regarding the sale of the securities covered by this prospectus. At any time a particular offer of the securities covered by this prospectus is made, a revised prospectus or prospectus supplement, if required, will set forth the aggregate amount of securities covered by this prospectus being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers or agents. In addition, to the extent required, any discounts, commissions, concessions and other items constituting underwriters' or agents' compensation, as well as any discounts, commissions or concessions allowed or reallowed or paid to dealers, will be set forth in such revised prospectus supplement. Any such required prospectus supplement, and, if necessary, a post-effective amendment to the Registration Statement of which this prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the securities covered by this prospectus.

To the extent required, the applicable prospectus supplement will set forth whether or not underwriters may over-allot or effect transactions that stabilize, maintain or otherwise affect the market price of the securities at levels above those that might otherwise prevail in the open market, including, for example, by entering stabilizing bids, effecting syndicate covering transactions or imposing penalty bids.

If we utilize a dealer in the sale of the securities being offered pursuant to this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

We may also authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the revised prospectus or prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The conditions to these contracts and the commission that we must pay for solicitation of these contracts will be described in a revised prospectus or prospectus supplement.

In connection with the sale of the securities covered by this prospectus through underwriters, underwriters may receive compensation in the form of underwriting discounts or commissions and may also receive commissions from purchasers of securities for whom they may act as agent. Underwriters may sell to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agent.

Any underwriters, broker/dealers or agents participating in the distribution of the securities covered by this prospectus may be deemed to be "underwriters" within the meaning of the Securities Act, and any commissions received by any of those underwriters, broker/dealers or agents may be deemed to be underwriting commissions under the Securities Act.

We may agree to indemnify underwriters, broker/dealers or agents against certain liabilities, including liabilities under the Securities Act, and may also agree to contribute to payments which the underwriters, broker/dealers or agents may be required to make.

Certain of the underwriters, broker/dealers or agents who may become involved in the sale of the securities may engage in transactions with and perform other services for us in the ordinary course of their business for which they receive customary compensation.

Some or all of the securities may be new issues of securities with no established trading market. Any underwriters that purchase the securities for public offering and sale may make a market in such securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We make no assurance as to the liquidity of or the trading markets for any securities.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us LaBarge Weinstein LLP, Ottawa, Ontario. Underwriters, dealers or agents, if any, who we identify in a prospectus supplement may have their own counsel pass upon certain legal matters in connection with the shares of common stock offered under this prospectus.

EXPERTS

The consolidated financial statements of Fennec Pharmaceuticals Inc. appearing in Fennec Pharmaceuticals Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2016, have been audited by Deloitte LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference in reliance upon the authority of said firm as experts in accounting and auditing.

Shares

FENNEC PHARMACEUTICALS INC.

Common Shares

PROSPECTUS SUPPLEMENT

April , 2020

Cantor

Wedbush PacGrow