Aralez Pharmaceuticals Inc.
Form POS AM
March 18, 2016
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As filed with the Securities and Exchange Commission on March 18, 2016

Registration No. 333-208821

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

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-1
ON
FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

ARALEZ PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

British Columbia, Canada	**2834**	**98-1283375**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

151 Steeles Avenue East

Milton, Ontario, Canada L9T1Y1

(905) 876-1118
(Address, including zip code, and telephone number,
including area code, of registrant s principal executive offices)

Adrian Adams

Chief Executive Officer

Aralez Pharmaceuticals Inc.

3 Columbus Circle, Suite 1710

New York, New York 10019

(732) 754-2545
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:
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Short Hills, New Jersey 07078

(973) 520-2550

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large accelerated filer	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	o

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), SHALL DETERMINE.

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EXPLANATORY NOTE

This Post-Effective Amendment No. 1 on Form S-3 relates to the registration statement on Form S-1 (File No. 333-208821) of Aralez Pharmaceuticals Inc. (we , us , our , the Company or Aralez), which was declared effective by the Securities and Exchange Commission on February 5, 2016 (the Registration Statement).

Aralez is filing this post-effective amendment to the Registration Statement (the Post-Effective Amendment) for the purpose of 1) updating the associated financial statements, including information from the Company s Annual Report on Form 10-K for the year ended December 31, 2015, including the financial statements for that period, and 2) converting the Registration Statement on Form S-1 into a Form S-3. **NO NEW OR ADDITIONAL SECURITIES ARE BEING REGISTERED UNDER THIS POST-EFFECTIVE AMENDMENT.**

Aralez became eligible to utilize Form S-3 for this purpose on February 5, 2016, as a result of completing a business combination transaction, described below, pursuant to which Tribute Pharmaceuticals Canada Inc., a corporation incorporated under the laws of the Province of Ontario, Canada (Tribute) and POZEN Inc., a Delaware corporation (Pozen) were combined under and became subsidiaries of the Company. Pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended (the Exchange Act), the Company is the successor issuer to Pozen, an entity which was eligible to utilize Form S-3.

The prospectus included in this Post-Effective Amendment relates to the distribution of up to 7,200,000 of the Company s common shares by QLT Inc. (QLT or the Selling Shareholder) to its shareholders, which were previously registered upon the original filing of this Registration Statement on Form S-1, and constitutes a post-effective amendment to such Registration Statement.

The Shares were issued to the Selling Shareholder pursuant to the Amended and Restated Share Subscription Agreement dated December 7, 2015 (the Amended and Restated Subscription Agreement) by and among Aralez, Aralez Pharmaceuticals plc, the Selling Shareholder, Tribute, Pozen, and the following investors: Deerfield Private Design Fund III, L.P. (Deerfield Private Design), Deerfield International Master Fund, L.P. (Deerfield International), Deerfield Partners, L.P. (Deerfield Partners), Broadfin Healthcare Master Fund, Ltd, JW Partners, LP, JW Opportunities Master Fund Ltd., and JW Opportunities Fund, LLC (collectively, the Investors).

This Post-Effective Amendment shall hereafter become effective concurrently with the effectiveness of this Registration Statement in accordance with Section 8 of the Securities Act.

This Post-Effective Amendment should be read in conjunction with the Registration Statement. This Post-Effective Amendment does not reflect events that may have occurred after the date of the Registration Statement and does not modify or update in any way the disclosures made in the Registration Statement, except as required to reflect the revisions discussed above.

The information included in this filing updates and supplements this Registration Statement and the Prospectus contained therein. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale of these securities is not permitted.

Subject to Completion, Dated March 18, 2016

PROSPECTUS

7,200,000 Shares

ARALEZ PHARMACEUTICALS INC.

Common Shares

This prospectus relates to the distribution of up to 7,200,000 of our Common Shares, no par value per share (the Common Shares), by QLT to its shareholders, as further described under the section entitled Plan of Distribution on page 31 of this prospectus. Our Common Shares covered by this prospectus (the Shares) were issued by us to the Selling Shareholder following the arrangement and private placement pursuant to the Amended and Restated Share Subscription Agreement, each as more fully described in this prospectus.

Our Common shares currently trade on the NASDAQ Global Market (NASDAQ) under the symbol ARLZ and on the Toronto Stock Exchange (TSX) under the symbol ARZ. On March 16, 2016, the closing price of our Common Shares was $4.19 per share.

INVESTING IN OUR COMMON SHARES INVOLVES RISKS. QLT SHAREHOLDERS SHOULD CAREFULLY CONSIDER THE RISKS THAT WE HAVE DESCRIBED IN RISK FACTORS ON PAGE 10 OF THIS PROSPECTUS, AND UNDER SIMILAR HEADINGS IN ANY AMENDMENTS OR SUPPLEMENTS TO THIS PROSPECTUS, BEFORE VOTING ON THE QLT PLAN OF ARRANGEMENT OR ELECTING TO RECEIVE THE SHARES FROM QLT.

Neither the Securities and Exchange Commission nor any state securities commission, nor any securities regulatory authority in Canada, has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus or determined that this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment. Neither we nor the Selling Shareholder have authorized anyone to provide you with different information. The Selling Shareholder is not making an offer of its Shares in any state where such offer is not permitted.

The date of this prospectus is March 18, 2016

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CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and documents incorporated by reference into this prospectus and any prospectus supplement or free writing prospectus may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), Section 21E of the Exchange Act, and within the meaning of applicable securities laws in Canada. Forward-looking statements include, but are not limited to, statements about the expected benefits of the Tribute Transaction (as defined below), including growth potential, our strategies, plans, objectives, financial forecasts, goals, prospects, prospective products or product approvals, future performance or results of current and anticipated products, exposure to foreign currency exchange rate fluctuations, interest rate changes and other statements that are not historical facts, and such statements are typically identified by use of terms such as may, will, would, should, could, expect, plan, intend, an believe, estimate, predict, likely, potential, continue or the negative or similar words, variations of these words or other comparable words phrases, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Investors should note that many factors, as more fully described in the documents we file with the Securities and Exchange Commission (SEC) and securities regulatory authorities in Canada, including under the heading Risk Factors in our Form 10-K and those described from time to time in our future reports filed with the SEC and securities regulatory authorities in Canada, and as otherwise enumerated herein or therein, could affect future financial results and could cause actual results to differ materially from those expressed in forward-looking statements contained in this prospectus. Important factors that, individually or in the aggregate, could cause actual results to differ materially from expected and historical results include, but are not limited to:

- our ability to achieve significant upside potential for shareholders by obtaining approval of product candidates, including YOSPRALA, and by accelerating the growth of our products;

- our ability to acquire new products or companies on terms acceptable to us;

- our ability to sustain and grow revenues and cash flow from operations in our markets and to maintain and grow our customer base, the need for innovation and the related capital expenditures and the unpredictable economic conditions in the United States, Canada and other markets;

- the impact of competition from other market participants;

- the development and commercialization of new products, including YOSPRALA (upon approval), Fibricor, our Canadian product portfolio and others;

- the effects of governmental regulation on our business or potential business combination transactions;

- changes in tax laws or interpretations that could increase our consolidated tax liabilities, including changes in tax laws that would result in us being treated as a domestic corporation for United States federal tax purposes;

- the availability and access, in general, of funds to meet our debt obligations prior to or when they become due and to fund our operations and necessary capital expenditures, either through (i) cash on hand, (ii) free cash flow or (iii) access to the capital or credit markets; and

- our ability to comply with all covenants under existing credit facilities, any violation of which, if not cured in a timely manner, could trigger a default of its other obligations under cross-default provisions.

Other unknown or unpredictable factors could also have material adverse effects on our future results, performance or achievements. All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We do not assume any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

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PROSPECTUS SUMMARY

No person has been authorized to give any information or make any representation concerning us, the Selling Shareholder or the Shares to be registered hereunder (other than as contained in this prospectus). You should rely only on the information contained in this prospectus and the documents incorporated by reference herein and any prospectus supplement and, if any such other information or representation is given or made, you should not rely on it as having been authorized by us or the Selling Shareholder.

The Selling Shareholder is offering the Shares only in jurisdictions where such issuances are permitted. The distribution of this prospectus and the sale of the Shares in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the distribution of this prospectus and the sale of the Shares outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the Shares by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Except as otherwise noted, all references to dollars or $ in this prospectus are to United States dollars. Unless the context otherwise requires, references in this prospectus to we, us and our refer to Aralez and its subsidiaries.

Overview

Incorporation and Registered Office

Aralez was incorporated under the British Columbia *Business Corporations Act* (BCBCA) on December 2, 2015. Our registered office is located at 666 Burrard Street, Suite 1700, Vancouver, British Columbia, V6C 2X8 and our principal executive offices are located at 151 Steeles Avenue East, Milton, Ontario, Canada, L9T 1Y1, 3 Columbus Circle, Suite 1710, New York, New York, 10019, and 56 Fitzwilliam Square, Dublin 2, Ireland.

Our Company

Aralez is a global specialty pharmaceutical company focused on delivering meaningful products to improve patients lives while focusing on creating shareholder value by acquiring, developing and commercializing products primarily in cardiovascular, pain and other specialty areas. Our global headquarters is located in Ontario, Canada, its U.S. headquarters is located in New York, New York and its Irish headquarters is located in Dublin, Ireland. Aralez was formed for the purpose of facilitating the business combination of POZEN Inc., a Delaware corporation (Pozen), and Tribute Pharmaceuticals Canada Inc., a corporation incorporated under the laws of the Province of Ontario, Canada (Tribute), which business combination was consummated on February 5, 2016. We have had no operations as of December 31, 2015, other than business incident to the Tribute Transaction (as defined below).

Our management team has a strong track record of success in creating, leading and expanding specialty pharmaceutical companies with marketing and sales capabilities. Directed by this leadership and leveraging our competitive platform, our focus on acquiring high potential growth opportunities through aggressive business development and licensing and strategic M&A and commercializing healthcare products to provide enhanced value to a range of stakeholders is driven by the following primary strategies:

- *Maximize value of expanded portfolio* We plan to continue our progress toward building out our U.S. commercial organization, including growing our sales force and promoting the use of Fibricor® in the United States to grow product use moderately in the United States and which we expect will develop a relationship springboard with cardiologists ahead of the anticipated approval and commercial launch of YOSPRALA .

- *Business development through selective acquisitions* We have completed numerous transactions over the past few years to expand our portfolio offering. We will continue to pursue value-driven business development opportunities as they arise and enhance our product pipeline and expand our geographic footprint through strategically acquiring low-risk, revenue generating product candidates or approved products, particularly in the cardiovascular and pain anchor areas, but also in other specialty therapeutic areas that we anticipate are or will become revenue generating and accretive.

- *Leverage platform for growth* We intend to maintain a lean, nimble and performance-oriented operating model with strong financial discipline. Our well-capitalized financial profile provides us with ample liquidity to commercialize YOSPRALA, if and when approved, and creates the opportunity for sustained long-term growth, both organically and through acquisitions, while also enabling us to have an ongoing focus on growing shareholder value.

On February 5, 2016, pursuant to the Merger Agreement (as defined below) Aralez completed the acquisition of Tribute by way of a court approved plan of arrangement in a stock transaction with an estimated purchase price of $138 million made up of (i) $115 million related to Tribute shares, equity awards and certain warrants outstanding and (ii) $23 million in repayments of Tribute indebtedness. In connection with the transaction, Pozen and Tribute were combined under and became subsidiaries of Aralez

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Pharmaceuticals Inc., with Pozen treated as the acquiring company for accounting purposes (the Tribute Transaction). Pursuant to Rule 12g-3(a) under the Exchange Act, Aralez Pharmaceuticals Inc. is the successor issuer to Pozen. The Tribute Transaction provides the combined company with increased financial strength and product portfolio diversity and is expected to meaningfully accelerate our operating strategies.

On June 8, 2015, Pozen entered into an Agreement and Plan of Merger and Arrangement (the Original Merger Agreement), among Tribute, Aguono Limited (which was renamed Aralez Pharmaceuticals Limited and subsequently renamed Aralez Pharmaceuticals plc in connection with its re-registration as a public limited company), a limited company incorporated in Ireland (Former Parent), Trafwell Limited, a private limited company incorporated in Ireland, ARLZ US Acquisition Corp., a corporation incorporated under the laws of the State of Delaware and a wholly-owned subsidiary of Former Parent, and ARLZ CA Acquisition Corp., a corporation incorporated under the laws of the Province of Ontario and a wholly-owned subsidiary of Former Parent (Can Merger Sub) in order to effectuate the merger of Pozen and Tribute. On December 7, 2015, the Original Merger Agreement was amended, (the Merger Agreement) pursuant to which, among other things, (i) the Company replaced Former Parent as a party to the Original Merger Agreement, whereby, after giving effect to the merger transactions, the Company would be the ultimate parent company of the combined companies, (ii) ARLZ US Acquisition II Corp., a corporation formed under the laws of the State of Delaware, would be merged with and into Pozen, with Pozen continuing as the surviving corporation and an indirect wholly-owned subsidiary of the Company, and (iii) Can Merger Sub and Tribute would amalgamate, with the separate legal existence of Can Merger Sub ceasing and Tribute and Can Merger Sub continuing as one corporation and as a wholly-owned subsidiary of the Company (the arrangement).

Products

Primary Commercialized Products

Products Marketed in the United States

Fibricor® and Authorized Generic

In May 2015, we acquired the U.S. rights to Fibricor (fenofibric acid) and its related authorized generic. Fibricor is indicated as a complementary therapy along with diet for the treatment of severe hypertriglyceridemia and as a complementary therapy along with diet to reduce elevated low-density lipoprotein (LDL) cholesterol (LDL-C), total cholesterol (Total-C), triglycerides (TG), and apolipoprotein B (Ap B), and to increase high-density lipoprotein (HDL) cholesterol (HDL-C) in patients with primary hypercholesterolemia or mixed dyslipidemia. Fibricor is currently protected by four U.S. patents extending to August 20, 2027.

Fibricor is a lipid-regulating agent available as tablets for oral administration. Fibrates like Fibricor, activate peroxisome proliferator activated receptor (PPAR) alpha, increasing the activity of lipoprotein lipase. This typically causes a decrease in triglyceride levels. PPAR alpha activation also increases HDL production. Each tablet contains 35mg or 105mg fenofibric acid, and the 35mg tablet is the lowest dose of fenofibric acid available in the United States. Fibricor is contraindicated in patients with severe renal impairment, active liver disease, liver function abnormalities, preexisting gallbladder disease or known hypersensitivity to fenofibric acid or fenofibrate.

Hyperlipidemia Treatment Options: Hyperlipidemia is a very common chronic condition and is characterized by an excess of fatty substances called lipids, mainly cholesterol and triglycerides, in the blood. It is also called hyperlipoproteinemia because these fatty substances travel in the blood attached to proteins. This is the only way that these fatty substances can remain dissolved while in circulation. Hyperlipidemia, in general, can be divided into two subcategories: (1) hypercholesterolemia, in which there is a high level of cholesterol; and (2) hypertriglyceridemia, in which there is a high level of triglycerides, the most common form of fat. In general, lifestyle modifications such as diet, exercise and smoking cessation are the first line of treatment. If unsuccessful, pharmacologic therapy is commonly utilized for the treatment of primary and secondary dyslipidemias. In managing secondary dyslipidemia, statin therapy is commonly prescribed. For the management of major triglyceride elevations, three agents are also commonly utilized: (1) fibric acid derivatives, such as Fibricor; (2) niacin; and (3) omega-3 fatty acids. Fibricor is approved in the United States and indicated as adjunctive therapy to diet for treatment of severe hypertriglyceridemia (TG $\geq$ 500 mg/dL) and as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, TG, and Apo B, and to increase HDL-C in patients with primary hypercholesterolemia or mixed dyslipidemia.

Competitive Analysis: Cholesterol-lowering drugs in the United States include statins, niacin, bile-acid resins, fibric acid derivatives (fibrates), cholesterol absorption inhibitors, and anti-protein convertase subtilisin-like kexin type 9 (PCSK9) inhibitors. All classes of cholesterol-lowering medicines are most effective when combined with increased exercise and a low-fat, high-fiber diet. The statin class includes some of the largest-selling prescription products in the world (e.g., Lipitor®, Zocor® and Crestor®). Statins dominate single-agent prescribing for the treatment of lipid disorders. The niacin (nicotinic acid vitamin B3) class includes brands such as Niaspan®, which work primarily on increasing HDL cholesterol. The cholesterol absorption inhibitor class has a single product, Zetia®. The PCSK9 inhibitor are a new class of treatments that currently include Praluent® and Repatha™. The fibrates class

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of cholesterol lowering treatments is composed of three competing molecules: (1) gemfibrozil (Lopid®), (2) fenofibric acid (Fibricor, Trilipix®), and (3) fenofibrate (Tricor®). The fibrate market in the United States was $2.4 billion for 2015.

Products Marketed in Canada

Cambia®

Cambia (diclofenac potassium for oral solution) is a non-steroidal anti-inflammatory drug (NSAID) and the only prescription NSAID available and approved in Canada for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. Cambia was licensed from Nautilus Neurosciences, Inc. (Nautilus) in November 2010. Cambia was approved by the FDA in June 2009 and is currently marketed by Depomed, Inc. (Depomed) in the United States. Cambia was approved by Health Canada in March 2012 and was commercially launched to specialists in Canada in October 2012 and broadly to all primary care physicians in February 2013. Depomed acquired Nautilus and the U.S. and Canadian rights to Cambia in December 2013.

Cambia is available as an oral solution in individual packets each designed to deliver a 50mg dose when mixed in water. Cambia is the only approved prescription NSAID available in Canada that was studied and proven to be an effective treatment for migraine according to guidelines published in September 2013 by the International Headache Society that reached statistically significant results for all four co-primary endpoints, including: (1) pain free response at two hours; (2) nausea free; (3) photophobia free (sensitivity to light); and (4) phonophobia free (sensitivity to sound). In addition, Cambia provides fast migraine pain relief within 30 minutes of dosing due in part to the significant benefits of the proprietary Dynamic Buffering Technology (DBT). DBT provides for enhanced drug absorption and bioavailability. In fasting volunteers, measurable plasma levels were observed within 5 minutes of dosing with Cambia. Peak plasma levels were achieved at approximately 15 minutes, with a range of approximately 10 to 40 minutes. NSAIDs, such as Cambia, may increase the incidence of cardiovascular adverse events such as myocardial infarction (MI), stroke or thrombotic events, gastrointestinal adverse events such as peptic/duodenal ulceration, perforation and gastrointestinal bleeding and are contraindicated in the third trimester of pregnancy. The risk may increase with duration of use and patients should only take this medication as prescribed by a physician.

Migraine Treatment Options in Canada: There are a number of different treatment options for migraine in Canada. Acute migraine treatment options can be broken down to three main categories: (i) triptans or 5-HT1 receptor agonists (e.g., sumatriptan, rizatriptan); (ii) ergot alkaloids (ergots) (e.g., ergotamine, dihydroergotamine); and (iii) NSAIDs (e.g., Cambia). Triptans may cause dizziness, nausea, weakness and chest discomfort and should not be used by patients with heart disease, uncontrolled high blood pressure, blood vessel disease or who have a history of stroke. Ergots may cause chest pain, tingling or burning sensations, nausea, vomiting, and cramps. Furthermore, ergots may reduce blood flow to the extremities (hands and feet) and may lead to tissue damage. Ergots should also not be used by anyone with heart disease, uncontrolled high blood pressure or blood vessel disease.

In September 2013, the Canadian Neurological Sciences Federation issued revised Canadian Headache Society Guidelines for Acute Drug Therapy for Migraine Headaches through the Canadian Journal of Neurological Sciences. Cambia was acknowledged as a potential first line

therapy, with a fast onset of action and having a strong recommendation, high quality evidence and recommended for the acute treatment of migraine.

Migraine in Canada: Canadian studies have shown migraine prevalence rates of 23% to 26% in women, and 8% to 10% in men. Over 4,000,000 Canadians suffer from migraine in Canada and that 60% of those with migraine have one or more attacks per month while 25% of those with migraine have at least one attack per week. One Canadian study found that those with migraine lose 6.5 days of work each year resulting from their migraine and, as a result, migraine is associated with a substantial social and economic impact. A study done in 1990 calculated that 7,000,000 workdays are lost annually in Canada due to migraine. It was also found that 51% of all women suffering from migraine have never consulted a physician for their headaches.

Competitive Analysis: It is estimated that one-half of all people suffering from migraines in Canada never seek help from a physician but rather self-treat their condition with over-the-counter (OTC) medications such as aspirin (e.g., Bayer®), acetaminophen (e.g., Tylenol®) and OTC NSAID s such as ibuprofen (e.g., Advil®) and naproxen sodium (e.g., Aleve®). The main prescription pharmacological agents used to treat acute migraine includes the triptan class of drugs or 5-HT1 receptor agonists as they are known and these products include sumatriptan (Imitrex®), rizatriptan (Maxalt®), zolmitriptan (Zomig®), almotriptan (Axert®), naratriptan (Amerge®), eletriptan (Relpax®) and frovatriptan (Frova®). There are also the ergot alkaloids such as ergotamine (Cafergot®) and dihydroergotamine (Migrinal®) used in some cases as are narcotics such as meperidine (e.g., Demerol®) and the combination drug of aspirin, butalbital and caffeine (e.g., Fiorinal). In spite of a number of possible treatment options for treating migraines, many of these treatments are without an authorized indication from Health Canada. The Company considers the competitive market as the triptans class, which currently sells approximately $125 million annually in Canada.

Fiorinal®/Fiorinal® C

Fiorinal (acetylsalicylic acid, caffeine and butalbital tablets and capsules) and Fiorinal C (acetylsalicylic acid, caffeine, butalbital and codeine capsules) were acquired from Novartis AG and Novartis Pharma AG in October 2014. Fiorinal and Fiorinal C

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were originally approved by Health Canada in 1970 for the relief of tension-type headache.

Fiorinal is a fixed dose combination drug that combines the analgesic properties of acetylsalicylic acid, with the anxiolytic and muscle relaxant properties of butalbital, and the central nervous system stimulant properties of caffeine. Fiorinal C expands on the properties of Fiorinal with the additional analgesic effect of codeine. Fiorinal and Fiorinal C are the only prescription products in Canada indicated for relief of tension type headaches. Fiorinal and Fiorinal C are currently marketed in Canada in hard gelatin capsules containing 330mg acetylsalicylic acid, 40mg caffeine, 50mg butalbital, and in the case of Fiorinal C, the addition or 15mg or 30mg of codeine. Codeine and butalbital are both habit-forming and potentially abusable. Consequently, the extended use of Fiorinal or Fiorinal C is not recommended. Fiorinal and Fiorinal C are associated with exacerbation of headache (medication overuse headaches) in susceptible patients. Repeated use of Fiorinal and Fiorinal C can lead to rebound headaches as each dose wears off. With repeated doses physical and psychological dependence can develop. In addition to dependence, butalbital-containing products can lead to tolerance, and at higher doses can produce withdrawal symptoms after discontinuation.

Tension-Type Headache in Canada: Tension-type headaches are the most common type of headache and are caused by muscle tightening in the back of the neck or scalp. These headaches are typically triggered by emotional stress, fatigue or depression. There are two classifications of tension-type headache: (1) episodic tension headaches, which occur randomly and less frequently; and (2) chronic tension headaches, which may occur daily or continually and the intensity of the pain may vary during a 24-hour cycle. Tension headaches differ from migraine headaches due to the lack of aura, photophobia, phonophobia and/or nausea.

Competitive Analysis: Tension-type headaches may be treated with OTC NSAIDs like Tylenol®, Advil®, Aleve®, or Aspirin®. Prescription NSAIDs may also be used, such as Naprosyn®, Anaprox®, Toradol®, as well as prescription analgesic/opiate combinations like Percocet®, Tylenol® with codeine and Fiorinal/Fiorinal C. In spite of a number of possible treatment options for treating tension-type headaches, all of these treatments, with the exception of Fiorinal and Fiorinal C, are without an authorized indication from Health Canada. The Company considers the competitive market as the prescription NSAID and prescription analgesic/opiate combination class, which has an estimated tension-type headache value of approximately $30 million annually in Canada. The OTC market for tension-type headache is estimated to be exponentially larger given the large patient population; however, the true value is extremely difficult to determine considering the broad range of indications for OTC NSAIDs.

Soriatane®

Soriatane (acitretin) is chemically known as acitretin, and is indicated for the treatment of severe psoriasis (including erythrodermic and pustular types) and other disorders of keratinization. Soriatane is a retinoid, an aromatic analog of vitamin A. Soriatane was approved in Canada in 1994 and is the first and only oral retinoid indicated for psoriasis. Soriatane is often used when milder forms of psoriasis treatments like topical steroids, emollients and topical tar-based therapies have failed.

Soriatane should be reserved for patients unresponsive to, or intolerant of, standard treatment. In addition, Soriatane should only be prescribed by physicians knowledgeable in the use of systemic retinoids. Soriatane is teratogenic (can cause birth defects) and should not be used by

women who are pregnant or who are planning to become pregnant during, or within three years after stopping, treatment of Soriatane. In addition, acitretin may cause nausea, headache, itching, dry, red or flaky skin, dry or red eyes, dry or chapped lips, swollen lips, dry mouth, thirst, cystitis acne or hair loss.

Psoriasis Treatment Options: There are a number of different treatment options for psoriasis. Typically, topical agents are used for mild disease, phototherapy for moderate disease and oral systemic agents and biologicals for more severe disease. The three main traditional systemic treatments are (1) methotrexate, (2) cyclosporine and (3) retinoids. Unlike Soriatane, methotrexate and cyclosporine are immunosuppressant drugs. Methotrexate may cause a decrease in the number of blood cells made by bone marrow, may cause liver damage, lung damage, damage to the lining of the mouth, stomach or intestines and may increase the risk of developing lymphoma (cancer that begins in the cells of the immune system), among other serious side effects. Methotrexate may also cause serious or life-threatening skin reactions. Cyclosporines may cause side effects that could be very serious, such as high blood pressure and kidney and liver problems. It may also reduce the body s ability to fight infections.

Competitive Analysis: Severe psoriasis is a condition that involves more than 10% of the body area or is physically, occupationally or psychologically disabling. Soriatane will typically be used in combination with other drugs such as topical steroids, emollients or tar-based therapies. Soriatane is most effective for treating psoriasis when it is used with phototherapy. Soriatane may be used with biologic agents, such as etanercept (Enbrel®), adalimumab (Humira®) or infliximab (Remicade®), and may also be prescribed in rotation with cyclosporine or methotrexate. Biologic therapies such as Enbrel®, Humira® and Remicade® are effective in treating severe forms of the disease, but tend to be very expensive and sometimes not reimbursed by government or other private drug plans. Cyclosporine and methotrexate are also oral agents that are often used for severe forms of psoriasis. The market for moderate to severe psoriasis in Canada, including the biologics, is estimated to be greater than $200 million for 2015.

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Bezalip® SR

Bezalip SR (bezafibrate) is an established pan-peroxisome proliferator-activated receptor activator. Bezalip SR, used to treat hyperlipidemia (high cholesterol), has over 25 years of therapeutic use globally. Bezalip SR helps lower LDL-C and triglycerides while raising HDL-C levels. It also improves insulin sensitivity and reduces blood glucose levels, which in combination with the cholesterol effects may significantly lower the incidence of cardiovascular events and development of diabetes in patients with features of metabolic syndrome. Bezalip SR is contraindicated in patients with hepatic and renal impairment, pre-existing gallbladder disease, hypersensitivity to bezafibrate, or pregnancy or lactation.

Bezalip SR is currently approved in more than 40 countries worldwide, not including the United States. Bezalip SR is under license from Actavis Group PTC (Actavis), and we have the exclusive rights to market Bezalip SR in Canada. We also have the exclusive development and licensing rights to Bezalip SR in the United States and filed an Investigational New Drug (IND) that received clearance from the FDA in the United States. Clinical studies would be required prior to commercialization in the United States. The initial target indication that would be considered for pursuit in the United States is for severe hypertriglyceridemia.

Hyperlipidemia Treatment Options: Hyperlipidemia is a very common chronic condition and is characterized by an excess of fatty substances called lipids, mainly cholesterol and triglycerides, in the blood. It is also called hyperlipoproteinemia because these fatty substances travel in the blood attached to proteins. This is the only way that these fatty substances can remain dissolved while in circulation. Hyperlipidemia, in general, can be divided into two subcategories: (1) hypercholesterolemia, in which there is a high level of cholesterol; and (2) hypertriglyceridemia, in which there is a high level of triglycerides, the most common form of fat.

Competitive Analysis: Cholesterol-lowering drugs in Canada include statins, niacin, bile-acid resins, fibric acid derivatives (fibrates), and cholesterol absorption inhibitors. All classes of cholesterol-lowering medicines are most effective when combined with increased exercise and a low-fat, high-fiber diet. The statin class includes some of the largest-selling prescription products in the world (e.g., atorvastatin (Lipitor®), simvastatin (Zocor®) and rosuvastatin (Crestor®)). Statins dominate single-agent prescribing for the treatment of lipid disorders. The niacin (nicotinic acid vitamin B3) class includes brands such as Niaspan®, which work primarily on increasing HDL cholesterol. The fibrates class of cholesterol-lowering treatments is composed of three competing molecules: (1) gemfibrozil (Lopid®), (2) bezafibrate (Bezalip SR), and (3) fenofibrate (Lipidil® in Canada or Tricor® in the United States). Clinical studies have demonstrated that bezafibrate, the active ingredient in Bezalip SR, was shown to be effective in lowering high levels of triglycerides, raising HDL cholesterol and lowering LDL cholesterol. As of the end of 2015, the annual fibrate market in Canada is estimated to be approximately $35 million.

Other Commercialized Products

In addition to the products discussed above, we also market NeoVisc® (sodium hylauronic solution - 1%), Uracyst® (sodium

chondroitin sulfate - 2%), Durela® (tramadol hydrochloride), Proferrin® (heme iron polypeptide), Resultz® (isopropyl myristate), Collatamp® G (collagen-gentamycin) and a portfolio of eight products targeted in the gastroenterology and women s health markets in Canada.

Primary Development Products

YOSPRALA

The products in the YOSPRALA (aspirin/omeprazole delayed release tablets) portfolio, which are part of our proton pump inhibitor (PPI)-aspirin (PA) platform, are being developed with the goal of significantly reducing gastrointestinal (GI) ulcers and other GI complications compared to taking enteric-coated, buffered or plain aspirin alone in patients at risk of developing GI ulcers. The first candidates in the YOSPRALA product portfolio are YOSPRALA 81/40 (PA8140), which contains 81mg of enteric-coated aspirin and 40mg immediate-release omeprazole, and YOSPRALA 325/40 (PA32540), which contains 325mg of enteric-coated aspirin and 40mg immediate-release omeprazole. Both products are a coordinated-delivery tablet combining immediate-release omeprazole, a PPI, layered around a pH-sensitive enteric coating of an aspirin core. This novel, patented product is intended for oral administration once a day.

Pending FDA review and approval, YOSPRALA 81/40 and 325/40 would be indicated for patients who require aspirin (1) to reduce the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, (2) to reduce the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, (3) to reduce the combined risk of MI and sudden death in patients with chronic stable angina pectoris, (4) for a pre-existing condition after having undergone revascularization procedures, and (5) the omeprazole component, to decrease the risk of developing gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers.

Development History and Status: YOSPRALA 81/40 and 325/40 products have completed Phase 3 clinical development testing in the United States, and we resubmitted the NDA for these products with the FDA on March 14, 2016.

We met with the FDA to discuss the overall development program requirements for YOSPRALA 81/40 and 325/40 for the

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secondary prevention of cardiovascular and cerebrovascular disease in patients at risk for gastric ulcers. An IND was filed in the fourth quarter of 2007. We completed a study which demonstrated that the salicylic acid component of YOSPRALA 325/40 was bioequivalent to the reference drug, enteric-coated aspirin. We filed a Special Protocol Assessment with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in the cumulative incidence of endoscopic gastric ulcers.

In October 2009, we began two pivotal Phase 3 and one long-term safety study for YOSPRALA 325/40. The primary endpoint of the pivotal studies, which included approximately 500 subjects per study, was a significant reduction in the cumulative incidence of gastric ulcers following administration of YOSPRALA 325/40 compared to 325mg enteric-coated aspirin over the six-month treatment period. The primary endpoint was met with statistical significance in both studies. Additionally, the studies met their key secondary endpoints, including a reduction in gastroduodenal ulceration, as well as a reduction in discontinuation due to upper gastrointestinal adverse events in subjects taking YOSPRALA 325/40 compared to 325mg enteric-coated aspirin.

In February 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of YOSPRALA 325/40 to enteric-coated aspirin 325mg with respect to acetylsalicylic acid. After the Company completed the requested bioequivalence study, the FDA made a preliminary review of the study results and the Company s summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of YOSPRALA 325/40 to enteric-coated aspirin 325mg was demonstrated. The Company then submitted to the FDA additional information and analyses from the requested bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a briefing document in support of a request for a Type A meeting with the FDA. At the Type A meeting held in August 2012 (the August 2012 Type A Meeting), the FDA confirmed that, although it believes bioequivalence of YOSPRALA 325/40 to enteric-coated aspirin 325mg was not strictly established in our bioequivalence study according to the predetermined criteria, the results from this study, together with additional information that was submitted by the Company in the NDA, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and enteric-coated aspirin 325mg. The FDA indicated that it would make a final determination during the NDA review. The FDA also indicated that a similar strategy to bridge to the reference listed drug, inclusive of a new, single pharmacokinetic study, could be utilized for a low dose version of the 325/40mg version, YOSPRALA 81/40. The Company conducted this study with the low dose version against the enteric-coated aspirin 81mg. Based on the predetermined criteria acceptable to the FDA, the study demonstrated that YOSPRALA 81/40 is bioequivalent to enteric-coated aspirin 81mg and had comparable bioavailability.

During a pre-submission meeting with respect to its NDA for YOSPRALA 325/40 in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81mg of enteric-coated aspirin as part of its NDA for YOSPRALA 325/40. Absent the availability of such a lower dose formulation in the market if YOSPRALA 325/40 is approved, the FDA indicated that it might limit the indication for YOSPRALA 325/40 to use in post coronary artery bypass graft surgery with treatment duration not to exceed one year. During the August 2012 Type A Meeting, the FDA confirmed its preference to have both YOSPRALA 325/40 and a lower dose version available in the market so that physicians can have both a low and high dose option available, and agreed that, if both dosage strengths were included in the NDA and subsequently approved, the indications for both will be consistent with the full range of indications described in the current aspirin monograph.

We had generated some clinical pharmacology data and chemical, manufacturing and controls (CMC) data for a lower dose version of YOSPRALA 325/40 a product that contains 81mg of enteric-coated aspirin and 40mg of immediate-release omeprazole in a single tablet known YOSPRALA 81/40. The Company filed this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81mg of aspirin with the FDA. At this time, we do not intend to conduct Phase 3 clinical trials for YOSPRALA 81/40. We have no assurance such data will be sufficient for the FDA to approve YOSPRALA 81/40 or to allow a broader indication for YOSPRALA 325/40. The FDA will make a final determination with respect to the approvability of and indications for YOSPRALA 325/40 and 81/40 upon our re-submission of the NDA, which we resubmitted with the FDA on March 14, 2016.

The generation of additional data with respect to YOSPRALA 81/40 and the incorporation of data into the NDA for YOSPRALA 325/40 delayed submission of the NDA from the original planned submission date in the third quarter of 2012. The NDA was filed for both products in March 2013, and in May 2013, the FDA accepted the NDA for review. The FDA assigned a user fee date of January 24, 2014. As part of our continuing discussions with the FDA concerning the NDA for YOSPRALA 325/40 and 81/40 tablets, we decided to conduct an additional comparative Phase 1 pharmacokinetic study to determine the pharmacokinetic profile of the omeprazole component of YOSPRALA 81/40 tablets and compare it to that of YOSPRALA 325/40 tablets. We submitted study information and data to the FDA as it became available during the conduct of the study and FDA reviewed such information and data from the study when submitted. The final study report was submitted to the FDA in accordance with our agreed timeline. The FDA informed us that the Company s user fee date was moved to April 25, 2014.

On April 25, 2014, we received a Complete Response Letter (CRL) from the FDA advising that the review of our NDA was completed and questions remained that preclude the approval of the NDA in its then current form. Specifically, an inspection of the manufacturing facility of our previously designated primary aspirin API supplier concluded with certain inspection deficiencies.

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There were no clinical or safety deficiencies noted with respect to either YOSPRALA 325/40 or 81/40 and no other deficiencies were noted in the CRL. On June 30, 2014, we resubmitted the NDA for YOSPRALA 325/40 and 81/40 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, the aspirin API supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response.

On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA was completed and questions remained that preclude approval of the NDA in its then current form. In this CRL, the FDA used identical wording to that of the first CRL. There were no clinical or safety deficiencies noted with respect to either YOSPRALA 325/40 or 81/40 and no other deficiencies were noted in the CRL. FDA regulations allowed us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA s Office of Compliance stated that the aspirin API supplier s responses to the 483 inspectional observations submitted in May 2014 were still under review and the Office of Compliance would be communicating with the supplier in the coming weeks. The aspirin API supplier subsequently informed us that it received a warning letter relating to the Form 483 inspection deficiencies and submitted a plan of corrective actions to the FDA to address the matters raised in the warning letter.

On December 28, 2015, we announced that the FDA had completed re-inspection of the aspirin API supplier s manufacturing facility and issued an additional 483 notice, citing numerous observations. The aspirin API supplier voluntarily stopped production at this facility to focus on remediating the FDA observations. We have been informed that production at this facility has resumed and it remains subject to FDA inspection.

On December 28, 2015, we also announced that significant progress had been made with respect to an alternative aspirin API supplier, which is a global leader in aspirin manufacturing, and that we have now designated this secondary supplier as our primary supplier in connection with the NDA for YOSPRALA. We are focusing our efforts toward using our previously designated secondary aspirin API supplier as our primary supplier in connection with our NDA and will include both aspirin API suppliers in the NDA package for YOSPRALA. Final agreement on the draft labeling is also pending. We resubmitted the NDA for YOSPRALA on March 14, 2016, and we believe we remain on track for potential approval and launch of YOSPRALA in 2016.

Bilastine

Bilastine is a second generation antihistamine drug for the treatment of allergic rhinoconjunctivitis and urticaria (hives). The Company has not yet chosen a trademark for bilastine. Bilastine exerts its effect as a selective histamine H1 receptor antagonist, and has an effectiveness similar to cetirizine, fexofenadine and desloratadine. It was developed in Spain by FAES Farma, S.A. The Canadian antihistamine market is currently valued at approximately $115 million per year and the leading competitors are cetirizine (Reactine®), loratadine (Claritin®), desloratadine (Aerius®) and fexofenadine (Allegra®). It has been over fifteen years since the approval of a new antihistamine in Canada.

The Company filed bilastine with Health Canada in the second quarter of 2015. Bilastine is approved in the European Union for the symptomatic treatment of allergic rhinoconjunctivitis and urticaria, but it is not approved by the FDA for any use in the United States.

The clinical efficacy of bilastine in allergic rhinitis (AR) and urticaria has been assessed in 10 clinical studies in which over 4,600 patients were involved. The studies on seasonal AR (SAR) were double-blind, placebo-controlled, parallel-group involving male and female patients over 12 years of age with symptomatic disease at the beginning of the study. In the SAR studies, the daily oral administration during 14 days of bilastine 20mg proves to have comparable efficacy to the administration of cetirizine 10mg or than the administration of desloratadine 5mg. Bilastine 20mg shows a safety and tolerability profile similar to placebo. Possible side effects of bilastine include headache and drowsiness.

The studies in urticaria were double-blind, placebo-controlled, parallel-group involving male and female patients over 18 year of age with symptomatic disease (chronic idiopathic urticaria) at the beginning of the study. In this urticaria studies the daily oral administration of 28 days of bilastine 20mg proves to have comparable efficacy to the administration of levocetirizine 5mg. Likewise, bilastine 20mg shows a safety and tolerability profile comparable to placebo.

Out-Licensed Products

VIMOVO®

VIMOVO (naproxen/esomeprazole magnesium) is the brand name for a proprietary fixed-dose combination of enteric-coated naproxen, a pain-relieving NSAID and immediate-release esomeprazole magnesium, a PPI, in a single delayed-release tablet and is a product in our PPI-NSAID (PN) platform. We developed VIMOVO in collaboration with AstraZeneca AB (AstraZeneca). On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric

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ulcers. As of the end of December 31, 2015, VIMOVO is being sold in over 50 countries. Prescription sales of oral anti-arthritis NSAIDs in the United States in 2015 were approximately $6.3 billion.

In June 2010, we officially transferred to AstraZeneca the IND and NDA for the product. AstraZeneca is responsible for the commercialization of VIMOVO. In November 2013, AstraZeneca entered into an agreement for Horizon Pharma USA, Inc. (Horizon) to acquire the U.S. rights for VIMOVO. Under the terms of the agreement, we will continue to receive from Horizon a 10% royalty on net sales of VIMOVO sold in the United States, with guaranteed annual minimum royalty payments of $5 million in 2014, and $7.5 million each year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are on the market. AstraZeneca will continue to have rights to commercialize VIMOVO outside of the United States and paid us a royalty of 6% on all sales within its territory through 2015 and will pay us a royalty of 10% commencing 2016 and thereafter. See also the section entitled Item 1. Business Collaboration Agreements Agreement with AstraZeneca/Horizon regarding VIMOVO® in this Annual Report on Form 10-K.

Treximet®

Treximet (sumatriptan/naproxen sodium) is a migraine medicine that was developed by us in collaboration with Glaxo Group Limited, d/b/a GlaxoSmithKline (GSK). The product is formulated with our patented technology of combining a triptan, sumatriptan 85mg, with an NSAID, naproxen sodium 500mg, and GSK s RT Technology in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the FDA approved Treximet for the acute treatment of migraine attacks, with or without aura, in adults. Treximet is available in the United States. The market for migraine medications in the United States is valued at approximately $2.2 billion in 2015.

In May 2008, we transferred the IND and NDA for the product to GSK, which subsequently sold its rights in Treximet, including the related trademark, to Pernix Therapeutics Holdings, Inc. (Pernix) in August 2014. As part of GSK s divestiture to Pernix, restrictions on our right to develop and commercialize certain additional dosage forms of sumatriptan/naproxen combinations outside of the United States had been eliminated, allowing us to seek approval for these combinations on the basis of the approved NDA. GSK was previously, and Pernix is currently, responsible for the commercialization of Treximet in the United States, while we received royalties based on net sales. In November 2011, we sold to a financial investor, CPPIB Credit Investments Inc. (CII), for an upfront lump-sum, our rights to future royalty and milestone payments relating to Treximet sales in the United States and certain other products containing sumatriptan/naproxen sodium developed and sold by Pernix in the United States. By virtue of the agreement, we will also be entitled to receive a 20% interest in royalties, if any, paid on net sales of Treximet and such other products in the United States to CII relating to the period commencing in the second quarter of 2018. See also the section entitled Item 1. Business Collaboration Agreements Agreements with GSK, Pernix and CII regarding MT 400 (including Treximet®) in this Annual Report on Form 10-K.

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RISK FACTORS

Investing in our Common Shares involves a high degree of risk. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors in its entirety, in addition to other information contained in this prospectus, as well as our other public filings with the SEC and securities regulatory authorities in Canada. The risks and uncertainties described below are those we currently believe to be material, but they are not the only ones we face. If any of the following risks, or any other risks and uncertainties that we have not yet identified or that we currently consider not to be material, actually occur or become material risks, our business and financial condition could be materially and adversely affected.

Risks Related to Our Business

Our ability to generate revenues from our products is subject to attaining significant market acceptance among physicians, patients, third-party payors and the medical community.

Our current products, and other products or product candidates that we may develop, acquire or in-license, may not attain market acceptance among physicians, patients, third-party payors or the medical community. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of a product will not be known until after it is launched and a product may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the acceptance by primary care doctors and other medical specialists of our products, including VIMOVO, Fibricor, our Canadian product portfolio and YOSPRALA, if and when approved, as an alternative to other therapies;
- the receipt and timing of regulatory approvals;
- the timing of market introduction of our products as well as competitive drugs;
- the availability of coverage and adequate reimbursement and pricing from government and other third-party payors;
- the price of our products, both in absolute terms and relative to alternative therapies;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;
- the availability of alternative therapies;
- the extent and effectiveness of marketing efforts by our collaborators, third-party distributors and agents;
- the strength of sales, marketing and distribution support;
- the existence of adverse publicity regarding our products or similar products and the pricing of pharmaceutical products generally;
- the efficacy of our products compared to alternative therapies; and
- the extent and severity of side effects as compared to alternative therapies.

If we make strategic acquisitions, we will incur a variety of costs and may fail to realize all of the anticipated benefits of the transactions or those benefits may take longer to realize than expected. We may be unable to identify, acquire, close or integrate acquisition targets successfully.

A significant part of our business strategy includes acquiring and integrating complementary businesses, products, technologies or other assets, and forming strategic alliances and other business combinations, to help drive future growth. We may also in-license new products or compounds. Acquisitions or similar arrangements may be complex, time-consuming and expensive, and the process of negotiating the acquisition and integrating an acquired product, drug candidate, technology, business or company might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we may never realize the anticipated benefits of any acquisition or forecasted sales may not materialize. For example, in 2015, we acquired the rights to manufacture, market, promote, distribute and sell Fibricor and its related authorized generic in the United States from Sun Pharmaceuticals Industries Ltd. We may not realize the anticipated benefits of, and could be subject to additional liabilities relating to, such acquisition, which could have a material adverse effect on our financial condition.

In addition, there are a number of risks and uncertainties relating to our closing transactions. If such transactions are not completed for any reason, we will be subject to several risks, including the following: (i) the market price of our common shares may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our common shares; and (ii) many costs relating to the such transactions may be payable by us whether or not such transactions are completed.

If an acquisition is consummated, the integration of the acquired business, product or other assets into the Company may also be complex and time-consuming and, if such businesses, products and assets are not successfully integrated, we may not achieve the

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anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following: integrating personnel, operations and systems, while maintaining focus on selling and promoting existing and newly-acquired products; coordinating geographically dispersed organizations; distracting management and employees from operations; retaining existing customers and attracting new customers; maintaining the business relationships the acquired company has established, including with healthcare providers, third-party payors and distributors; and managing inefficiencies associated with integrating the operations of the Company.

Furthermore, we have incurred, and may incur in the future, restructuring and integration costs and a number of non-recurring transaction costs associated with these acquisitions, combining the operations of the Company and the acquired company and achieving desired synergies. These fees and costs may be substantial. Non-recurring transaction costs include, but are not limited to, fees paid to legal, financial, regulatory, manufacturing and accounting advisors, filing fees and printing costs. Additional unanticipated costs may be incurred in the integration of the businesses of the Company and the acquired company. There can be no assurance that the elimination of certain duplicative costs, as well as the realization of other efficiencies related to the integration of the acquired business, will offset the incremental transaction-related costs over time. Therefore, any net benefit may not be achieved in the near term, the long term or at all.

Finally, these acquisitions and other arrangements, even if successfully integrated, may fail to further our business strategy as anticipated or to achieve anticipated benefits and success, expose us to increased competition or challenges with respect to our products or geographic markets, and expose us to additional liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair our ability to realize any benefit from our acquisition or arrangement after we have expended resources on them.

The recently consummated Tribute Transaction represents a significant acquisition for the Company and may expose us to a number of the risks identified above. We may face difficulties in connection with the integration of the Tribute business into the Company, which integration activities may be complex, time-consuming and disruptive to the operation of our business generally. In addition, the costs incurred in connection with such integration activities may be more substantial than we have anticipated and, as a result, may significantly reduce or even outweigh any benefits and efficiencies realized during our integration efforts. Finally, we may not be successful in implementing all of our plans with respect to the Tribute business and, as a result, we may not be able to achieve all of the anticipated benefits of the Tribute Transaction. Any of these factors could have a material adverse effect on our business, financial condition or results of operations or could decrease or delay the expected accretive effect of the Tribute Transaction or cause the market value of our common shares to decline.

Failure to successfully acquire, license or develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to acquire, license or develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may depend upon pharmaceutical, biotechnology and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, license and/or acquire promising pharmaceutical or other healthcare product candidates and products for Canada, the United States and elsewhere. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights

to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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Further, any unapproved product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by applicable regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by applicable regulatory authorities.

We currently depend and will in the future depend on third parties to manufacture our products and product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our products and candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture our products or product candidates. We rely upon third-party manufacturers and our partners to supply us with the commercial and developmental supplies of our products and product candidates. For example, we have a supply agreement with Patheon, pursuant to which Patheon manufactures our requirements for the sale of YOSPRALA in the United States once approved. The manufacturing facilities of our contract manufacturers must be inspected and found to be in full compliance with cGMP, quality system management requirements or similar standards before marketing approval, and we may not be able to ensure that such third parties comply with these obligations. The failure of our contract manufacturers to comply with cGMP regulations, quality system management requirements or similar regulations could result in enforcement action by the FDA or its foreign counterparts, including, but not limited to, warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of products, total or partial suspension of production or importation, suspension or withdrawal of regulatory approval for approved or in-market products, refusal of the government to renew marketing applications, licenses or approve pending applications or supplements, suspension of ongoing clinical trials, imposition of new manufacturing requirements, closure of facilities and criminal prosecution. These enforcement actions could lead to a delay or suspension in production. Furthermore, the failure of our ingredient or material suppliers to comply with regulatory requirements can impact our ability to obtain approval of our products or our ability to supply the market with our products after approval. For example, in connection with the approval process for YOSPRALA, our initial primary aspirin API supplier had informed us that it received warning letters from the FDA relating to Form 483 inspection deficiencies. While the manufacturer is working to remediate these deficiencies, we have focused our efforts toward using our previously designated secondary aspirin API supplier as our primary supplier in connection with our re-submission of the YOSPRALA NDA.

There is no guarantee that manufacturers and API or other material suppliers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if Patheon is or our YOSPRALA API suppliers are, or any of our future contract manufacturers or API suppliers are, unable to satisfy our requirements or meet any regulatory requirements, and we are or will be required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

In the event that suppliers of a product, ingredient or any materials we need to manufacture or package our products or licensed products are not available or not for sale at the time we need such ingredient or material in order to meet our required delivery schedule or on commercially reasonable terms, then we could be at risk of a product shortage or stock-out. We rely on our suppliers in many cases to ensure the adequate supply of ingredients, APIs and packaging material and for the timely delivery of orders placed by us. Should we experience a shortage in supply of a product, licensed product, or API, any material sales of such product or licensed product could be harmed or reduced and our ability to generate revenues from such product or licensed product may be impaired.

We depend heavily on the success of our unapproved product candidates, which may never be approved for commercial use. Failure to successfully commercialize our products or develop, gain approval of or commercialize our product candidates would adversely impact our financial condition and prospects.

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful commercialization of our products upon regulatory approval in territories where our products are not approved, such as YOSPRALA in the United States. Before we can market and sell our products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the United States, Health Canada in Canada and from similar foreign regulatory agencies in other jurisdictions), and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain approval in those countries where we wish to commercialize our products. Even if we or our commercialization partners obtain additional regulatory approvals, we may never generate significant revenues from any commercial sales of our products. These approvals may not be granted on a timely basis, if at all. Nor can any assurance be given that if such approval is secured, the approved labeling will not have significant labeling limitations, including limitations on the indications for which we can market a product, or require onerous risk management programs. Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates. If we fail to successfully commercialize our current and future products, we

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may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

In addition, if our development projects are not successful or are significantly delayed, we may not recover our substantial investments in the product candidates and our failure to bring these product candidates to market on a timely basis, or at all, could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline. For example, the approval process for YOSPRALA has been delayed due to Form 483 inspection deficiencies noted by the FDA to our previously designated primary aspirin API supplier. While the manufacturer is working to remediate these deficiencies, we have focused our efforts toward using our previously designated secondary aspirin API supplier as our primary supplier in connection with our YOSPRALA NDA. We will include both aspirin API suppliers in the NDA package for YOSPRALA.

We continue to evaluate the commercial opportunities for our current products and product candidates in connection with our development of a worldwide commercialization strategy. If we are unable to develop sales and marketing capabilities on our own, or through partnerships, we will not be able to fully exploit the commercial potential of our future products and the costs of pursuing such a strategy may have a material adverse impact on our results of operations.

We continue to evaluate the commercial opportunities for our products and product candidates in connection with our development of a worldwide commercialization strategy. In June 2015, our Board appointed Adrian Adams as our new Chief Executive Officer and Andrew I. Koven as our new President and Chief Business Officer, each of whom has experience creating, leading and expanding pharmaceutical companies with marketing and sales capabilities. We have retained ownership of our PA product candidates through the clinical development and pre-commercialization stage and have developed the commercialization strategy for these products and conducted all the required pre-commercialization activities in the United States. We plan to make significant expenditures to secure commercial resources to sell YOSPRALA once approved and the products we acquired from Tribute and to expand or enhance our marketing capabilities to support our anticipated growth. Any failure or extended delay in the expansion or enhancement of our sales and marketing capabilities or inability to effectively operate in the marketplace alone or together with our partners could adversely impact our business. There can be no assurance that our sales and marketing efforts will generate significant revenues and costs of pursuing such a strategy may have a material adverse impact on our results of operations. Events or factors that may inhibit or hinder our commercialization efforts include:

- building and developing our own commercial team or playing a role in the commercialization with a partner will be expensive and time-consuming and will result in high cash burn or reduced profitability;
- failure to acquire sufficient or suitable personnel to establish, oversee, or implement our commercialization strategy;
- failure to recruit, train, oversee and retain adequate numbers of effective sales and marketing personnel;
- failure to develop a commercial strategy ourselves or together with partners that can effectively reach and persuade adequate numbers of physicians to prescribe our products;
- our or our partners inability to secure reimbursement at a reasonable price;
- unforeseen costs and expenses associated with creating or acquiring and sustaining an independent commercial organization;

- incurrence of costs in advance of anticipated revenues and subsequent failure to generate sufficient revenue to offset additional costs; and

- ability to fund our commercialization efforts alone or together with our partners on terms acceptable to us, if at all.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products will be harmed.

We are required to expend significant time and resources to train our sales force to be credible, compliant and persuasive in educating physicians to prescribe and pharmacists to dispense our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. This is particularly true with respect to our products that have competing products prescribed to similar patients. 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 our products and their proper administration and approved indications, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

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Our reliance on collaborations with third parties to develop, manufacture and commercialize our development products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

With respect to the products we have out-licensed or developed internally, we depend upon collaborations with third parties to develop and manufacture these product candidates and, in some cases, we depend substantially upon third parties to commercialize these products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and possibly future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and may in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, the identification of new compounds or product candidates for development has led us in the past, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. For products we out-license, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us after a specified notice period for any reason or upon a default by us. For example, AstraZeneca, Horizon and Pernix have the right to terminate their respective agreements with us upon a 90-day notice for any reason. Contractors or collaborators may have the right to reduce their payments to us under their agreements. For example, Pernix, AstraZeneca and Horizon have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors enter the market and attain a pre-determined share of the market for products marketed under the agreements, or if they must pay a royalty to one or more third parties for rights they license from those third parties to commercialize products marketed under the agreements. Further, our current or future collaboration agreements may terminate, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates or our contract manufacturers inability to manufacture our products or to supply the sufficient quantities of our products to meet market demand. If our current or future collaborators exercise termination rights they may have, or if the agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

Collaborators may decide not to continue marketing our products in certain countries of the territory, as was the case when AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the United States and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. In addition, collaborators may decide to assign their rights under our agreement to third parties. For example, we had a collaboration agreement with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology, including Treximet, in the United States, and GSK subsequently divested all of its rights, title and interest to develop, commercialize and sell the licensed products in the United States to Pernix.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;

- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;

- third parties may not fulfill their regulatory or other obligations;

- we may not realize the contemplated or expected benefits from collaborative or other arrangements;

- if any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated;

- our collaborators may be able to exercise control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement; and

- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive from our collaborators, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

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We may not be able to compete with treatments now being developed and marketed, or which may be developed and marketed in the future by other companies.

Our products and product candidates will compete with existing and new therapies and treatments. There are also likely to be numerous competitors that are engaged in the development of alternatives to our technologies and products, which could render our products, product candidates and technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies, biotechnology companies, universities and public and private research institutions. Some of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Collaborations or mergers between large pharmaceutical or biotechnology companies with competing drugs and technologies could enhance our competitors financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing drugs or technologies, obtaining patent protection, obtaining regulatory approval for products, commercializing products or gaining market acceptance more rapidly than we can. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we experienced as a result of the CRL we received from the FDA relating to the NDA for YOSPRALA 325/40 and 81/40, increase this risk.

The competition for VIMOVO, and any other PN products that may be developed and receive regulatory approval, may come from the oral NSAID market, specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX-2 inhibitor, Celebrex®. The competition for our PA product candidates may come from aspirin itself, as well as other products used for secondary prevention.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

For certain of our products, we depend on reimbursement from third-party payors and a failure to obtain coverage or reduction in the extent of reimbursement could reduce our product sales and revenue.

Sales of certain of our products are dependent, in part, on the availability and extent of reimbursement from government health administration authorities, private health insurers and other organizations and our continued participation in such programs. These entities may refuse to provide coverage and reimbursement, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, including in the form of higher mandatory rebates or modified pricing terms.

In certain countries, including Canada, where we sell or are seeking or may seek to commercialize our products, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. A significant reduction in the amount of reimbursement or pricing for our products in one or more countries may reduce our

profitability and adversely affect our financial condition. Certain countries establish pricing and reimbursement amounts by reference to the price of the same or similar products in other countries. If coverage or the level of reimbursement is limited in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in current or new territories. In the United States, the EU member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. In the United States, for example, the price of drugs has come under intense scrutiny by the U.S. Congress. Third-party payors decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payors are increasingly challenging the prices charged for healthcare products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs.

Changes in government regulations or private third-party payors reimbursement policies may reduce reimbursement for our products and adversely affect our future results. Our commercial success depends on obtaining and maintaining reimbursement at anticipated levels for our products. It may be difficult to project the impact of evolving reimbursement mechanics or the willingness of payors to cover our products. If we are unable to obtain or maintain coverage, or coverage is reduced in one or more countries, our pricing may be affected and our product sales, results of operations or financial condition could be harmed.

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Failure to be included in formularies developed by managed care organizations, governments, hospitals and other organizations may negatively impact the utilization of our products, which could harm our market share and negatively impact our business, financial condition and results of operations.

Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be harmed, as could our business, financial condition, results of operations and cash flows.

For example, in July 2014, CVS Caremark and Express Scripts, Inc. removed VIMOVO from their formularies and placed it on the exclusion list. Horizon, who holds the U.S. commercialization rights for VIMOVO in exchange for royalty payments to us, estimated that approximately 20-30% of VIMOVO prescriptions in the United States could be impacted. While there was a 26% drop in VIMOVO prescriptions in the United States in the first quarter of 2015, we have seen growth in the remainder of the year such that the reported VIMOVO prescriptions by IMS Health Holdings, Inc. s National Prescription Audit for 2015 exceed the prescriptions for 2014 by 25%. However, net sales upon which we are paid royalty only rose by 2%, indicating that managed care is having an impact on the realization of price increases through formulary control.

Generic competition of our products could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

Upon the expiration or loss of patent protection for our products, or upon the at-risk launch (despite pending patent infringement litigation against the generic product) by a generic competitor of a generic version of our products, we can lose a significant portion of sales of that product in a very short period, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

If we lose our license from any licensors, we may be unable to continue a substantial part of our business.

We have licensed certain assets, including certain intellectual property, marketing authorizations and related data, and medical commercial and technical information, used in a substantial part of our business. Such license agreements may be terminated by the licensor if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If a license agreement is terminated, then we may lose our rights to utilize the intellectual property and other assets covered by such agreement to manufacture, market, promote, distribute and sell the licensed products, which may prevent us from continuing a substantial part of our business and may result in a material and serious adverse effect on our financial condition, results of operations and any prospects for growth.

We will not be able to commercialize our product candidates if preclinical studies do not produce successful results or if clinical trials do not demonstrate safety and efficacy in humans.

We and our development partners, as applicable, conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our product candidates in order to obtain regulatory approval for the sale of our product candidates. Preclinical studies and clinical trials are expensive, can take many years and have uncertain outcomes. If clinical trials are unsuccessful, we will not be able to commercialize our product candidates and additional studies may be required.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our research and development and commercialization efforts as well as our ability to identify, acquire, close or integrate acquisition targets successfully.

We are highly dependent on the efforts of our key management, especially Adrian Adams, our Chief Executive Officer, and Andrew I. Koven, our President and Chief Business Officer. If we should lose the services of Mr. Adams or Mr. Koven, or are unable to replace the services of our other key personnel who may leave the Company, or if we fail to recruit other key scientific and commercial personnel, we may be unable to achieve our business objectives and growth strategies. There is intense competition for qualified scientific and commercial personnel. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and

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better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited.

Our business, financial condition and results of operations are subject to risks arising from the international scope of our operations.

Our international operations and any future international operations may expose us to risks that could negatively impact our future results. Our operations may not develop in the same way or at the same rate as might be expected in a country with an economy similar to the United States or Canada. The additional risks that we may be exposed to in these cases include, but are not limited to:

- tariffs and trade barriers;
- currency fluctuations, which could decrease the Company s revenues or increase its costs;
- regulations related to customs and import/export matters;
- tax issues, such as tax law changes and variations in tax laws;
- limited access to qualified staff;
- inadequate infrastructure;
- cultural and language differences;
- inadequate banking systems;
- different and/or more stringent environmental laws and regulations;
- restrictions on the repatriation of profits or payment of dividends;
- crime, strikes, riots, civil disturbances, terrorist attacks or wars;
- nationalization or expropriation of property;
- law enforcement authorities and courts that are weak or inexperienced in commercial matters; and
- deterioration of political relations among countries.

Any of these factors, or any other international factors, could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline. Similarly, adverse economic conditions impacting our customers in these countries or uncertainty about global economic conditions could cause purchases of our products to decline, which would adversely

affect our revenues and operating results. Any failure to attain our projected revenues and operating results as a result of adverse economic or market conditions could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

Due to the large portion of our business conducted in currency other than U.S. dollars, we have significant foreign currency risk.

Our consolidated financial statements are presented in accordance with U.S. generally accepted accounting principles, and we report, and will continue to report, our results in U.S. dollars. Some of our operations are conducted by subsidiaries in Canada and other countries outside of the United States. The results of operations and the financial position of these subsidiaries are recorded in the relevant foreign currencies and then translated into U.S. dollars. Any change in the value of the Canadian dollar or of the currencies in the other markets in which we operate against the U.S. dollar during a given financial reporting period would result in a foreign currency loss or gain on the translation of U.S. dollar denominated revenues and costs. The exchange rates between many of the currencies in the other markets in which we operate against the U.S. dollar have fluctuated significantly in recent years and may fluctuate significantly in the future. Consequently, our reported earnings could fluctuate materially as a result of foreign exchange translation gains or losses and may not be comparable from period to period.

We face market risks attributable to fluctuations in foreign currency exchange rates and foreign currency exposure on the translation into U.S. dollars of the financial results of our operations in Canada and Europe, including, for example, as a result of the recent strengthening of the U.S. dollar against other foreign currencies, including the Canadian dollar and the Euro. Exchange rate fluctuations could have an adverse effect on our results of operations. Both favorable and unfavorable foreign currency impacts to our foreign currency-denominated operating expenses are mitigated to a certain extent by the natural, opposite impact on our foreign currency-denominated revenue. In addition, the repurchase of principal under our U.S. dollar denominated debt may result in foreign exchange gains or losses for Canadian income tax purposes. One-half of any foreign exchange gains or losses will be included in our Canadian taxable income.

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Risks related to Legislation and Regulations

As we pursue commercialization of YOSPRALA (upon approval), Fibricor, our Canadian product portfolio and other opportunities for our future products ourselves, failure to comply with the laws governing the marketing and sale of such products may result in regulatory agencies taking action against us and/or our partners, which could significantly harm our business.

As we pursue commercialization of YOSPRALA (upon approval), Fibricor, our Canadian product portfolio and other future products, we will be subject to extensive regulation by the FDA, Health Canada and the governmental authorities in other countries. In particular, there are many federal, state, provincial and local laws that we will need to comply with if we become engaged in the marketing, promoting, distribution and sale of pharmaceutical products. If we fail to comply with U.S. and Canadian regulatory requirements and those in other countries where our products are sold, we could lose our marketing approvals or be subject to civil and/or criminal penalties, injunctions, fines or other sanctions. In addition, incidents of adverse drug reactions, unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or even lead to withdrawal of a product from the market. The imposition of one or more of these penalties could adversely affect our revenues and our ability to conduct our business as planned. As a condition to granting marketing approval of a product, the FDA and Health Canada may require a company to conduct additional clinical trials, the results of which could result in the subsequent loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy of a product. Compliance with the extensive laws and regulations to which we are subject is complicated, time-consuming and expensive. We cannot assure you that we will be in compliance with all potentially applicable laws and regulations. Even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated.

We are subject to various laws and regulations, including fraud and abuse laws, anti-bribery laws and privacy and security regulations, and a failure to comply with such laws and regulations or prevail in any litigation related to noncompliance could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

Pharmaceutical and biotechnology companies have faced lawsuits and investigations pertaining to violations of healthcare fraud and abuse laws, such as the federal False Claims Act, the federal Anti-Kickback Statute, the United States Foreign Corrupt Practices Act (the FCPA) and other federal, state and provincial laws and regulations. We also face increasingly strict data privacy and security laws in the United States, Canada and other countries, the violation of which could result in fines and other sanctions. The United States Department of Health and Human Services Office of Inspector General recommends, and increasingly states, that pharmaceutical companies have comprehensive compliance programs and disclose certain payments made to healthcare providers or funds spent on marketing and promotion of drug products. While we have developed a corporate compliance program, we cannot assure you that we or our employees or agents are or will be in compliance with all applicable federal, state, provincial or foreign regulations and laws. If we are in violation of any of these requirements or any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines, exclusion from federal healthcare programs or other sanctions.

The FCPA, the Canadian Corruption of Foreign Public Officials Act (the CFPOA) and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. Although we require our employees to consult with our legal department prior to making any payment or gift thought to be exempt under applicable law, there is no assurance that such policies or procedures will work effectively all of the time or protect us against liability under the FCPA and/or the CFPOA for actions taken by our employees and other intermediaries with respect to our business or any businesses that we may acquire. We may operate in parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different from the United States and Canada. We cannot assure you that our internal control policies and procedures will protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such

violations, could disrupt our business and result in criminal or civil penalties or remedial measures, any of which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

We are also subject to various privacy and security regulations, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (as amended, HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions (e.g., healthcare claims information and plan eligibility, referral certification and authorization, claims status, plan enrollment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the European Commission adopted the EU Data Protection Directive, as implemented into national laws by the EU member states, which imposed strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities

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from different EU member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of EU member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. In December 2015, a proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU Data Protection Regulation, which will be officially adopted in early 2016, will introduce new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The EU Data Protection Regulation, which will be applicable two years after the date of its publication in the Official Journal for the European Union, will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could adversely affect our financial condition, results of operations and cash flows.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably and could adversely affect our business.

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the Health Care Reform Act) may affect the operational results of companies in the pharmaceutical industry, including the Company and other healthcare-related industries, by imposing on them additional costs. Effective January 1, 2010, the Health Care Reform Act increased the minimum Medicaid drug rebates for pharmaceutical companies, expanded the 340B drug discount program, and made changes to affect the Medicare Part D coverage gap, or donut hole. The law also revised the definition of average manufacturer price for reporting purposes, which has the potential to affect the amount of our Medicaid drug rebates to states. Beginning in 2011, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Act also added substantial new provisions affecting compliance, some of which required the entire industry to modify business practices with healthcare practitioners. Pharmaceutical manufacturers are required in 2013 to comply with the federal Physician Payments Sunshine Act, which was passed as part of the Health Care Reform Act and requires pharmaceutical companies to monitor and report payments, gifts, the provision of samples and other remuneration made to physicians and other healthcare professionals and healthcare organizations.

We are unable to predict the future course of federal or state healthcare legislation. A variety of federal and state agencies are in the process of implementing the Health Care Reform Act, including through the issuance of rules, regulations or guidance that materially affect our business. The risk of our being found in violation of these rules and regulations is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. The Health Care Reform Act and further changes to healthcare laws or regulatory framework that reduce our revenues or increase our compliance or other costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows, and could cause the market value of our Common Shares to decline.

In Canada, patented drug products are subjected to regulation by the PMPRB pursuant to the *Patent Act* (Canada) and the Patented Medicines Regulations. The PMPRB does not approve prices for drug products in advance of their introduction to the market. The PMPRB provides

guidelines from which companies like us set their prices at the time they launch their products. All patented pharmaceutical products introduced in Canada are subject to the post-approval, post launch scrutiny of the PMPRB. Since the PMPRB does not pre-approve prices for a patented drug product in Canada, there may be risk involved in the determination of an allowable price selected for a patented drug product at the time of introduction to the market by the company launching such products in Canada. If the PMPRB does not agree with the pricing assumptions chosen by such company introducing a new drug product, the price chosen could be challenged by the PMPRB pursuant to the PMPRB initiating an investigation and, if it is determined, usually pursuant to an oral tribunal hearing, that the price charged is excessive, the price of the product may be reduced and a fine may be levied against the company for any amount deemed to be in excess of the allowable price determined. Drug products that have no valid patents are not subject to the PMPRB s jurisdiction.

Our status as a foreign corporation for U.S. federal tax purposes could be affected by IRS action or a change in U.S. tax law.

Although the Company is incorporated in Canada, the Internal Revenue Service (the IRS) may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended (the Code). A corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation for U.S. federal income tax purposes. As a result of the Company being an entity incorporated in the

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Province of British Columbia, it would generally be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception pursuant to which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal income tax purposes.

Under Section 7874 of the Code, the Company may be treated as a U.S. corporation for U.S. federal income tax purposes if former Pozen shareholders hold 80% or more of the vote or value of the Company s shares by reason of holding stock in Pozen immediately after the Tribute Transaction and the Company s expanded affiliated group after the Tribute Transaction does not have substantial business activities in Canada relative to its worldwide activities. As a result of the fact that the former shareholders of Pozen owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of the combined entity s stock immediately after the Tribute Transaction, we believe we qualify as a foreign corporation for U.S. federal income tax purposes following the Tribute Transaction. However, there can be no assurance that there will not exist in the future a subsequent change in the facts or in law, which might cause us to be treated as a domestic corporation for U.S. federal income tax purposes, including with retroactive effect.

Further, there can be no assurance that the IRS will agree with the position that the ownership test was satisfied. There is limited guidance regarding the application of Section 7874 of the Code, including with respect to the provisions regarding the application of the ownership test. If we were unable to be treated as a foreign corporation for U.S. federal income tax purposes, the benefits associated with enhanced global cash management, including increased liquidity resulting from access to cash generated by our non-U.S. subsidiaries, would be jeopardized.

Our tax position may be adversely affected by changes in tax law relating to multinational corporations, or increased scrutiny by tax authorities.

Under current law, we expect to be treated as a foreign corporation for U.S. federal tax purposes. However, changes to the rules in Section 7874 of the Code or the Treasury regulations promulgated thereunder could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such changes could have prospective or retroactive application. In addition, recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence, and such legislation, if passed, could have an adverse effect on us.

Moreover, the United States Congress, the Organization for Economic Co-operation and Development and other government agencies in Canada and other jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of base erosion and profit shifting, where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the United States, Canada and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and profitability.

We are subject to income taxes in Canada, the United States, and certain foreign jurisdictions. Our effective income tax rate in the future could be adversely affected by a number of factors including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws. We regularly assess all of these matters to determine the adequacy of our tax provision which is subject to discretion. If our assessments are incorrect, it could have an adverse effect on our business and financial condition.

There can be no assurance that income tax laws and administrative policies with respect to the income tax consequences generally applicable to us, to our subsidiaries, or to a U.S. or Canadian holder of Common Shares will not be changed in a manner which adversely affects holders of our Common Shares.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, Medicare, PMPRB obligations, governmental funded drug formularies or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and/or fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by Centers for Medicare and Medicaid Services (CMS) to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier

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periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price (ASP), or best price information to the government or made a misrepresentation in the reporting of our ASP, we may be liable for civil monetary penalties. Our failure to submit monthly/quarterly average manufacturer price, ASP, and best price data on a timely basis could result in a civil monetary penalty. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that a company must participate in the Department of Veterans Affairs Federal Supply Schedule (FSS) pricing program, established by Section 603 of the Veterans Health Care Act of 1992, to be eligible to have its products paid for with federal funds. If we overcharge the government in connection with our FSS contract, whether due to a misstated federal ceiling price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our approved products and product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state, provincial and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, federal, state, provincial or foreign authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers activities involving hazardous materials, our business and financial condition may be adversely affected.

Risks Related to Our Financial Position and Capital Requirements

We have incurred losses since inception and we may continue to incur losses for the foreseeable future.

We have a limited operating history and even less history operating as a combined organization following the Tribute Transaction. As of December 31, 2015, Pozen had net losses of approximately $37.8 million and, on a pro forma basis combined with Tribute, $44.6 million. Our

ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our products and product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts, the timing and amount of payments that we may receive from others and the timing of our commercial expenses, including increased expenses in connection with the anticipated approval and launch of YOSPRALA. If our licensed or marketed products do not perform well in the marketplace, our revenue will be impacted and our business could be materially harmed.

We have limited product revenues and other sources of revenues. Even if we achieve profitability in the future, we cannot be certain that we will sustain profitability, which would depress the market price of our Common Shares and could cause our investors to lose all or a part of their investment.

Our ability to become profitable depends upon our ability to generate revenues from sales of our products. Product revenue for products which we license out is dependent upon the commercialization efforts of our partners. One of our primary sources of revenue is the royalty payments that we may receive in connection with the commercialization of VIMOVO by AstraZeneca, outside of the United States (excluding Japan), and Horizon in the United States. In the event that AstraZeneca, Horizon or any other third-party with future commercialization rights to any of our products or product candidates fails to adequately commercialize those products or product candidates because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize our products or product candidates in the applicable jurisdictions would be limited, which would adversely affect our business, financial condition, results of operations and prospects. In addition, our ability to generate future revenues depends heavily on our success in:

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- commercialization of our existing products and any other product candidates for which we obtain approval or that we acquire;
- obtaining FDA, and potentially Health Canada and EU, approval for YOSPRALA;
- securing Canadian approval and potentially additional foreign regulatory approvals for Treximet; and
- developing, acquiring or in-licensing and commercializing a portfolio of other product candidates in addition to our current products.

Even if we do generate additional product sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our Common Shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We may need additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development or commercialization efforts.

In the future, we may need to raise additional funds to execute our evolving business strategy. We have incurred losses from operations since inception and we may continue to incur additional operating losses. Our actual capital requirements will depend upon numerous factors, including:

- completing the regulatory approval process, and any further required clinical development related thereto, for YOSPRALA and other product candidates;
- our ability to commercialize or arrange for the commercialization of our products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- the ability to acquire or in-license additional complementary products or products that augment our current product portfolio.

As of December 31, 2015, we had an aggregate of $25 million in cash and cash equivalents. In connection with the closing of the Tribute Transaction, we received $75 million equity investment and $75 million convertible debt. In addition, pursuant to a Second Amended and Restated Debt Facility Agreement (the Facility Agreement), dated December 7, 2015, among us, Pozen, Tribute and certain lenders party thereto, we can borrow up to an additional aggregate principal amount of $200 million for acquisitions. While we believe that we will have sufficient cash reserves and cash flow to fund our operations to the point of generating continuous positive cash flow based on our current expectations of continued revenue growth, we may need to raise additional capital if we choose to expand our commercialization or development efforts more rapidly than we presently anticipate, if we develop, acquire or in-license additional products or acquire companies or if our revenues do not meet expectations. In addition, our expenses might increase beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the FDA s (or its foreign equivalent) consideration, or reconsideration, of our regulatory filings for our product candidates. We are planning to commercialize our PA product candidates in the United States without a commercial partner and our expenses will increase relative to prior years as we continue the transition from a development company that licenses its product candidates to other companies into a fully integrated, specialty pharmaceutical company.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry, or generally, or due to other unforeseen developments in our business. Further, we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or delay, cut back or abandon our plans to grow the business through acquisition or in-licensing. We also could be required to:

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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Any of the above events could significantly harm our business, financial condition and prospects and cause the price of our Common Shares to decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish intellectual property rights to our product candidates.

Additional capital may be needed in the future to continue our planned operations. We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Covenants imposed by the Facility Agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

The Facility Agreement imposes various covenants that limit our ability and/or our subsidiaries ability to, among other things:

- consolidate or merge with or into another person;
- enter into certain transactions with affiliates;
- pay dividends or distributions;
- create, incur or suffer liens;
- create, incur, assume guarantee or be liable with respect to indebtedness;
- acquire assets or transfer products or material assets; and
- issue equity securities senior to our Common Shares or convertible or exercisable for equity securities senior to our Common Shares.

The covenants imposed by the Facility Agreement and our obligations to service our outstanding debt:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- may require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

If we are unable to successfully manage the limitations and decreased flexibility on our business due to our debt obligations, we may not be able to capitalize on strategic opportunities or grow our business to the extent we would be able to without these limitations. Our failure to comply with any of the covenants could result in a default under the Facility Agreement, which could permit the required lenders to declare all or part of any outstanding loans to be immediately due and payable.

Risks Related to Our Intellectual Property and Product Liability

We may become involved in infringement actions which are uncertain, costly and time-consuming and could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

The pharmaceutical industry historically has generated substantial litigation concerning the manufacture, use and sale of products, and we expect this litigation activity to continue. The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. In order to protect or enforce patent rights, we may initiate litigation against third parties. If we are not successful in defending an attack on our patents and maintaining exclusive rights to market one or more of our products still under patent protection, we could lose a significant portion of sales in a very short period. We may also become subject to infringement claims by third parties and may have to defend against charges that we violated patents or the proprietary rights of third parties. If we infringe the intellectual property rights of others, we could lose our right to develop or sell products, including our generic products, or could be required to pay monetary damages or royalties to license proprietary rights

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from third parties. The outcomes of infringement actions are uncertain and infringement actions are costly and divert technical and management personnel from their normal responsibilities.

Third parties seeking to market generic versions of branded pharmaceutical products in the United States often file Abbreviated New Drug Applications (ANDA) with the FDA (with a similar process in Canada and other foreign countries) containing a certification stating that the ANDA applicant believes that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed. Such certifications are commonly referred to as Paragraph IV certifications. We and Horizon are engaged in Paragraph IV litigations with several generic pharmaceutical companies with respect to our VIMOVO patents. We and AstraZeneca are also engaged in a proceeding in Canada with Mylan Pharmaceuticals ULC (Mylan Canada), which is seeking approval of its generic version of VIMOVO in Canada prior to the expiration of our Canadian patent. If we are unsuccessful in any of these proceedings, or once our or our licensors applicable patents expire, and the FDA or Health Canada approve a generic version of one of our marketed products, such an outcome would have a material adverse effect on sales of such product, our business and our results of operations.

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions. Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured. If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. For example, if we are unsuccessful in protecting our patents in the litigation against several generic pharmaceutical companies who have file ANDAs for VIMOVO, such companies could market a generic version of the product prior to the expiration of our patents.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid or unenforceable or will go unthreatened by third parties. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our products or any other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States may be able to be provoked by a third-party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications or, as in many jurisdictions, such as in Canada, the earlier filed third-party application may be cited against our patent application by a patent office in rejecting our application on the basis that the invention lacks novelty.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other jurisdictions, and the specific content of

patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, in 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was enacted, and it included a number of significant changes to patent law in the United States. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. For example, third parties have filed petitions seeking *Inter Partes* Review (IPR) of some of our VIMOVO patents and one of our Treximet patents. A number of these petitions have been denied while others are still pending or have resulted in reviews that are ongoing. Finally, the Leahy-Smith Act contains statutory provisions that require the United States Patent and Trademark Office to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation

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could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the Patient Protection and Affordable Care Act allows applicants seeking approval of biosimilar or interchangeable versions of biological products to initiate a process for challenging some or all of the patents covering the innovator biological product used as the reference product. This process is complicated and could result in the limitation or loss of certain patent rights. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Canada. As a result, we may encounter significant problems in protecting and defending our intellectual property in the United States, Canada and other countries. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. For example, since patent protection is territorial, the teachings of a U.S. patent will generally only be protected in the United States. If we do not have a corresponding patent in another jurisdiction, the teachings of the U.S. patent may be in the public domain in such jurisdiction and free for a third-party to practice. Changes in either patent laws or in interpretations of patent laws in the United States, Canada and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by the Company during the course of the party s relationship with the Company. We also typically obtain agreements from these parties, which provide that inventions conceived by the party in the course of rendering services to the Company will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to the Company. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside Canada and the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent business risk of exposure to significant product liability and other claims in the event that the use of our products caused, or is alleged to have caused, adverse effects. For example, we may be sued if any of our products or product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. The withdrawal of a product following complaints and/or incurring significant costs, including the requirement to pay substantial damages in personal injury cases or product liability cases, could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Shares to decline.

Our product liability insurance coverage may not be sufficient to cover our claims and we may not be able to obtain sufficient coverage at a reasonable cost in the future. We will explore, on an on-going basis, expanding our insurance coverage related to the sale of our future marketed products when we obtain marketing approval for such products and commercial sales of such products begin. However, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

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If our products or technologies are stolen, misappropriated or reverse engineered, others could use our products or licensed products to produce competing products or technologies.

Third parties, including our partners, contract manufacturers, contractors and others involved in our business often have access to our products, licensed products, and technologies. If our products, licensed products or technologies were stolen, misappropriated or reverse engineered, they could be used by other parties that may be able to reproduce our products, licensed products, or technologies for their own commercial gain. If this were to occur, it would be difficult for us to challenge this type of use, especially in countries with limited intellectual property protection.

Risks Related to Ownership of Our Common Shares

The price of our Common Shares could be volatile, which may result in significant losses to our shareholders.

The trading price of our Common Shares could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in the Risk Factors of this Annual Report on Form 10-K, these factors include:

- fluctuations in our operating results and revenues generated by our marketed products;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- prolonged stock shortages from third-party manufacturers;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- commercial success of VIMOVO and our other product candidates in the marketplace once approved;
- our ability to obtain approval for YOSPRALA;
- our ability to successfully launch YOSPRALA, if and when approved;
- generic introductions of existing marketed products with no generic competition;
- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners or our inability to obtain consents or achieve minimum licensing terms;
- announcements by our collaborative partners regarding our products or product candidates;
- developments in new or pending litigation;
- public concern as to the safety and efficacy of our products;
- our ability to acquire or license new products or companies and the perception of the value of such transactions, and our ability to integrate and grow such products or companies;
- the sale or attempted sale of a large amount of our Common Shares into the market; and
- general market conditions.

The Common Shares are listed on the NASDAQ Global Market and the Toronto Stock Exchange. Volatility in the market prices of our Common Shares may increase as a result of our Common Shares being listed on both the NASDAQ Global Market and the Toronto Stock Exchange because trading is split between the two markets, resulting in less liquidity on both exchanges. In addition, different liquidity levels, volume of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices.

In addition, the stock market in general, and the NASDAQ Global Market, the Toronto Stock Exchange and the stocks of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may adversely affect the market price of our Common Shares, regardless of our actual operating performance.

Sales of substantial amounts of shares of our Common Shares in the public market could cause our share price to decline.

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our Common Shares in the public market, the trading price of our Common Shares could decline. Following the Tribute Transaction, Deerfield Private Design Fund III, L.P. (Deerfield Private Design) and its affiliates will beneficially own approximately 9.985% of the Company. Pursuant to the Facility Agreement, except in certain limited circumstances, Deerfield Private Design and its affiliates may not acquire a number of our Common Shares that would exceed 9.985% of the total number of our Common Shares then issued (excluding treasury shares). Any sales of substantial amounts of our Common Shares in the public market, including sales or distributions of shares by Deerfield Private Design, or the perception that such sales or distributions might occur, could harm the market price of our Common Shares and could impair our ability to raise capital through the sale of additional equity securities. Further, shareholder ownership will be diluted if we raise additional capital by issuing equity securities. In addition, our Common Shares that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional

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Common Shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Common Shares could decline.

Anti-takeover provisions in our Articles and certain provisions under the BCBCA could prevent or delay transactions that our shareholders may favor and may prevent shareholders from changing the direction of our business or management.

Provisions of our Articles and certain provisions under the BCBCA may discourage, delay or prevent a merger or acquisition that our shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their shares, and may also frustrate or prevent any attempt by shareholders to change the direction or management of the Company. For example, these provisions:

- authorize the issuance of blank check preferred shares without any need for action by shareholders;
- require a 75% majority of shareholder votes cast in favor of a resolution to remove a director;
- require a 662/3% majority of shareholder votes cast in favor of a resolution to effect various amendments to our Articles;
- require that (i) in the case of shareholder action by written consent, a matter that would normally require an ordinary resolution shall require written consent by shareholders representing at least 662/3% of the votes entitled to be cast in favor of such resolution, and (ii) in the case of any other resolution of the shareholders, the written consent of shareholders representing 100% of the votes entitled to be cast in favor of such resolution;
- establish advance notice requirements for nominations for election to the board of directors; and
- require shareholder proposals for matters to be acted upon by shareholders at shareholder meetings to be submitted pursuant to, and in accordance with, the applicable provisions of the BCBCA for inclusion in the Company s proxy materials by a date that is not later than three months prior to the anniversary date of the prior year s shareholder meeting.

These provisions, among others, whether alone or together, could delay or impede hostile takeovers and changes in control or changes to the composition of our board of directors or management. Any provision of our constating documents that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their Common Shares and could also affect the price that some investors are willing to pay for our Common Shares.

Provisions of Canadian law may delay, prevent or make undesirable an acquisition of all or a significant portion of our Common Shares or assets.

The Investment Canada Act subjects an acquisition of control of us by a non-Canadian to government review if our enterprise value as calculated pursuant to the legislation exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant Minister is satisfied that the investment is likely to be of net benefit to Canada. This could prevent or delay a change of control and may eliminate or limit strategic opportunities for shareholders to sell their Common Shares.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our Common Shares less attractive to investors.

The Company is incorporated under the laws of the Province of British Columbia, Canada, and therefore certain of the rights of holders of its shares are governed by Canadian law, including the provisions of the BCBCA, and by our Notice of Articles and Articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations and these differences may make our Common Shares less attractive to investors.

An investor may be unable to bring actions or enforce judgments against us and certain of our directors.

The Company is incorporated under the laws of the Province of British Columbia. Some of our directors and officers reside principally outside of the United States and a substantial portion of our assets and a substantial portion of the assets of these persons are located outside the United States. Consequently, it may not be possible for an investor to effect service of process within the United States on us or those persons. Furthermore, it may not be possible for an investor to enforce judgments obtained in United States courts based upon the civil liability provisions of United States federal securities laws or other laws of the United States against us or those persons.

We do not expect to pay dividends for the foreseeable future, and our shareholders must rely on increases in the trading price of our Common Shares for returns on their investment.

Except for the $1.75 per share special cash distribution by Pozen on December 30, 2013 (representing a surplus of corporate cash and accounted for as a return of capital to stockholders), we have never paid cash dividends on our Common Shares and do not

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expect to pay dividends in the immediate future. We anticipate that the Company will retain all earnings, if any, to support our operations. Any future determination to pay dividends on our Common Shares will be at the sole discretion of the board of directors and will depend on, among other things, the Company s results of operations, current and anticipated cash requirements and surplus, financial condition, contractual restrictions and financing agreement covenants, solvency tests imposed by corporate law and other factors that the board of directors may deem relevant. Holders of our Common Shares must rely on increases in the trading price of our shares for returns on their investment in the foreseeable future. In addition, the Facility Agreement prohibits the Company from making any cash dividend or distributing any of its assets, including its intangibles, to any of its shareholders in such capacity or its affiliates, subject to certain exceptions. The Facility Agreement also includes restrictions on the Company from incurring liens and undertaking indebtedness, subject to certain exceptions, which limitations may further impact the ability of the Company to pay any future dividends. See - Covenants imposed by the Facility Agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected above.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we would not incur if we were a private company. In particular, the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC, applicable securities laws in Canada, the NASDAQ Global Market and the Toronto Stock Exchange and the NASDAQ Global Market, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. Further, these rules and regulations may lack specificity and are subject to varying interpretations. Their application in practice may evolve over time, as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions to such corporate governance standards.

In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act, National Instrument 52-109 - *Certification of Disclosures in Issuers Annual and Interim Filings* and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors audit of that assessment requires the commitment of significant financial and managerial resources. We consistently assess the adequacy of our internal controls over financial reporting, remediate any control deficiencies that may be identified, and validate through testing that our controls are functioning as documented. While we do not anticipate any material weaknesses, the inability of management to assess our internal controls over financial reporting as effective could result in adverse consequences to us, including, but not limited to, a loss of investor confidence in the reliability of our financial statements, which could cause the market price of our stock to decline. The existence of this or one or more other material weaknesses or significant deficiencies in our internal control over financial reporting could result in errors in our financial statements, and substantial costs and resources may be required to rectify any internal control deficiencies. Although we continually review and evaluate internal control systems to allow management to report on the sufficiency of our internal controls, we cannot assure you that we will not discover weaknesses in our internal control over financial reporting. Any such weakness or failure to remediate any existing material weakness could materially adversely affect our ability to comply with applicable financial reporting requirements and the requirements of our various agreements.

We are committed to maintaining high standards of corporate governance and public disclosure, and our efforts to comply with evolving laws, regulations and standards in this regard have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, the laws, regulations and standards regarding corporate governance may make it more difficult, or increasingly more expensive, for us to obtain director and officer liability insurance. Further, our board members and executive officers could face an increased risk of personal liability in connection with their performance of duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business. If we fail to comply with new or changed laws, regulations or standards of corporate governance, our business and reputation may be harmed.

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USE OF PROCEEDS

We will not receive any proceeds from the sale of any Shares by the Selling Shareholder.

The Selling Shareholder will receive all of the net proceeds from the sale of any Shares offered by it under this prospectus. The Selling Shareholder will pay any underwriting discounts and commissions and expenses incurred by the Selling Shareholder for brokerage, accounting, tax, legal services or any other expenses incurred by the Selling Shareholder in disposing of these Shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the Shares covered by this prospectus.

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SELLING SHAREHOLDER

The table below presents information regarding the Selling Shareholder and the Shares that such Selling Shareholder may distribute under this prospectus.

The following table sets forth:

- the name of the Selling Shareholder;
- the number of Common Shares beneficially owned by the Selling Shareholder prior to the distribution of the Shares covered by this prospectus;
- the number of Shares that may be offered by the Selling Shareholder pursuant to this prospectus;
- the number of Shares to be beneficially owned by the Selling Shareholder following the distribution of any Shares covered by this prospectus; and
- the percentage of our issued and outstanding Common Shares to be owned by the Selling Shareholder following the distribution of any Shares covered by this prospectus (based on Common Shares issued and outstanding as of March 15, 2016).

All information with respect to ownership of our common shares by the Selling Shareholder has been furnished by or on behalf of the Selling Shareholder, is as of March 15, 2016.

The Selling Shareholder has informed us that it proposes to effect a special pro-rata distribution to its shareholders in the amount of $45 million, payable at the election of each QLT shareholder either by a distribution by QLT of its Shares or in cash, provided that the aggregate cash amount to be distributed to its shareholders will not exceed $15 million (the Distribution).

Selling Shareholder	Common Shares beneficially owned prior to the offering	Number of Common Shares offered hereby	Number of Common Shares beneficially owned after the offering	% of class beneficially owned after the offering
QLT Inc.	7,200,000	7,200,000		

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PLAN OF DISTRIBUTION

Pursuant to our Amended and Restated Subscription Agreement with QLT and the Investors, Tribute sold to QLT and the Investors an aggregate of $75 million of Tribute common shares in a private placement at a purchase price per share equal to the exchange ratio of 0.1455 multiplied by the equity price, which is the lesser of (i) $7.20, and (ii) a 5% discount off the five day VWAP per share of Pozen common stock, calculated over the five trading days immediately preceding the date of closing of the merger, not to be less than $6.25. Upon consummation of the arrangement, Tribute common shares will be exchanged for Common Shares (the Subscription Shares).

QLT has informed us that it proposes to effect a special pro-rata distribution to its shareholders in the amount of $45 million, payable at the election of each QLT shareholder either by a distribution by QLT of its Subscription Shares or in cash, provided that the aggregate cash amount to be distributed to its shareholders will not exceed $15 million (the Distribution). The $15 million cash component would be funded exclusively pursuant to the terms of an agreement (the Backstop Agreement) dated June 8, 2015 and amended December 7, 2015 with each of the following (the Backstop Investors): Broadfin Healthcare Master Fund Ltd., JW Partners, LP and JW Opportunities Master Fund Ltd. Pursuant to the Backstop Agreement, the Backstop Investors agreed to purchase from QLT those Subscription Shares that the QLT shareholders have elected not to receive in the Distribution, up to a maximum of $15 million of Subscription Shares. The per share price to be paid by the Backstop Investors in exchange for the Subscription Shares will be equal to the price paid by QLT. As a result, QLT shareholders will be able to elect to receive their respective pro rata entitlement of the Distribution in cash instead of Subscription Shares, up to an aggregate amount of $15 million. The Amended and Restated Subscription Agreement also provides that we shall take all actions as may be necessary to elect, or cause to be elected, an individual designated by QLT to our board of directors effective upon issuance of the Subscription Shares to QLT.

The Distribution may be effected by way of a reorganization of QLT s share capital or other alternatives, all of which are subject to various conditions, including among other things, QLT obtaining shareholder approval by special resolution of a plan of arrangement at a special meeting of QLT shareholders currently anticipated to be held in the first quarter of 2016. If the QLT shareholders do not approve the treatment of the Distribution as a reorganization of QLT s share capital, the QLT board of directors intends to effect the Distribution by distributing the Subscription Shares and cash to the QLT shareholders as a dividend in kind.

Prior to effecting the Distribution, the QLT board of directors will set a record date for the purpose of determining the QLT shareholders entitled to participate in the Distribution. Following the record date for the Distribution, QLT s registrar and transfer agent, Computershare Investor Services Inc. (Computershare), will mail an election form to the QLT shareholders as of the record date pursuant to which each QLT shareholder will have an opportunity to elect to receive a portion of its pro rata entitlement of the Distribution in cash, subject to the maximum cash amount of $15 million. The QLT shareholders will have a certain period of time within which to return their election forms to Computershare. The QLT shareholders who (i) do not elect to receive a portion of their pro rata entitlement of the Distribution in cash, or (ii), do not return the completed election forms to Computershare within the specified time will, following the expiry of the election period, receive such number of Subscription Shares reflecting their pro rata entitlement of the Distribution.

The QLT shareholders who elect to receive their pro rata entitlement of the Distribution in cash will, following of the expiry of the election period, receive an amount in cash equal to the per share purchase price paid by QLT multiplied by the number of Subscription Shares that such QLT shareholder would have been entitled to receive reflecting their pro rata entitlement to the Distribution, provided that such cash amount shall be subject to pro ration as a result of the maximum cash amount of $15 million with the remainder to be paid in Subscription Shares.

The Distribution will be effected only following the completion of the issuance of the Subscription Shares to QLT and the formal approval by the QLT board of directors of the Distribution, including the establishment of a record date for such purposes.

QLT s ability to distribute the $15 million to its shareholders (in lieu of the Subscription Shares) is entirely dependent on the completion of the transactions under the Backstop Agreement. In the event the sale of the Subscription Shares to the Backstop investors does not complete for any reason, QLT shareholders will receive their entire pro rata entitlement to the Distribution in Subscription Shares, notwithstanding that they have elected to receive cash instead.

We have not employed any brokers, dealers or underwriters, nor are we paying any commissions, fees or discounts, in connection with the issuance of the Subscription Shares to QLT or the Distribution. QLT will bear all expenses arising in connection with the Distribution, except that we have agreed to bear all expenses arising in connection with the registration of the Subscription Shares, as further described in the Amended and Restated Subscription Agreement.

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INTERESTS OF NAMED EXPERTS AND COUNSEL

No expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis, or had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in the registrant or any of its parents or subsidiaries. Nor was any such person connected with the registrant or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer, or employee.

The validity of the issuance of the securities offered hereby will be passed upon for us by DLA Piper (Canada) LLP.

The consolidated financial statements of POZEN Inc. appearing in Aralez Pharmaceuticals Inc. s Annual Report (Form 10-K) for the year ended December 31, 2015, and the effectiveness of POZEN Inc. s internal control over financial reporting as of December 31, 2015 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, incorporated by reference therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

The balance sheet of Aralez Pharmaceuticals Inc. appearing in Aralez Pharmaceuticals Inc. s Annual Report (Form 10-K) for the year ended December 31, 2015, and the effectiveness of Aralez Pharmaceuticals Inc. s internal control over financial reporting as of December 31, 2015 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, incorporated by reference therein, and incorporated herein by reference. Such balance sheet is incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Tribute Pharmaceuticals Canada Inc. appearing in Aralez Pharmaceuticals Inc. s Current Report (Form 8-K/A) for the year ended December 31, 2015 have been audited by McGovern, Hurley, Cunningham LLP, independent registered public accounting firm, as set forth in their report thereon, incorporated by reference therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the SEC. You may read and copy any reports, statements or other information we file at the SEC s public reference rooms in Washington D.C., New York, New York and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our filings are also available to the public from commercial document retrieval services and at the web site maintained by the SEC at http://www.sec.gov. In addition, we maintain a website at http://www.aralez.com and make available free of charge on this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We are also required to file reports and other information with the securities commissions in all provinces in Canada, other than Quebec. You are invited to read and copy any reports, statements or other information, other than confidential filings, that we file with the provincial securities commissions (excluding the Autorité des marchés financiers). These filings are also electronically available from the Canadian System for Electronic Document Analysis and Retrieval (www.sedar.com), the Canadian equivalent of the SEC s electronic document gathering and retrieval system.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference much of the information we file with them under Commission File No. 00137691, which means that we can disclose important information to you by referring you to those publicly available documents. All of the information that we incorporate by reference is considered to be part of this prospectus, and any of our subsequent filings with the SEC will automatically update and supersede this information. This prospectus incorporates by reference all documents we file under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except for information furnished under Items 2.02 or 7.01 of Current Report on Form 8-K, or exhibits related thereto, after the date of this prospectus until the filing of a post-effective amendment to this prospectus which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold. We incorporate by reference the following previously filed documents:

- Our Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016;
- Our current reports on Form 8-K, filed on February 5, 2016, filed on March 7, 2016, filed on March 14, 2016, and the amendment to our current report on Form 8-K filed on March 15, 2016;
- The description of our Common Shares contained in our joint proxy statement/prospectus dated December 14, 2015 (File No. 333-208523); and

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- All other reports filed pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this registration statement and prior to the effectiveness of the registration statement.

We will provide, upon written or oral request, to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the documents incorporated by reference, including exhibits to these documents, at no cost to the requestor. You should direct any requests for documents to: Eric L. Trachtenberg, General Counsel, Chief Compliance Officer and Corporate Secretary, Aralez Pharmaceuticals Inc., 151 Steeles Avenue East, Milton, Ontario, Canada, L9T 1Y1, (905) 876-1118.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. We will not make an offer of these shares in any jurisdiction where the offer is not permitted. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. ***Other Expenses of Issuance and Distribution***

The following table sets forth an estimate of the costs and expenses payable by Aralez in connection with the offering described in this registration statement. All of the amounts shown are estimates except the SEC registration fee:

SEC Registration Fee(1)	$	4,924
Printing		25,000
Accounting Fees and Expenses		25,000
Transfer Agent and Registrar Fees		10,000
Legal Fees and Expenses		35,000
Miscellaneous		
Total	$	99,924

(1) Previously paid.

Item 15. ***Indemnification of Directors and Officers***

Subject to the provisions of and so far as may be admitted by the *Business Corporations Act* (British Columbia) (the BCBCA), every director and the secretary of the Company shall be entitled to be indemnified by the Company against all costs, charges, losses, expenses and liabilities incurred by him in the execution and discharge of his duties or in relation thereto including any liability incurred by him in defending any proceedings, civil or criminal, which relate to anything done or omitted or alleged to have been done or omitted by him as an officer or employee of the Company and in which judgment is given in his favor (or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on his part) or in which he is acquitted or in connection with any application under any statute for relief from liability in respect of any such act or omission in which relief is granted to him by the court.

In addition, as far as is permissible under the BCBCA, the Company shall indemnify any current or former executive officer of the Company (excluding any present or former directors of the Company or secretary of the Company), or any person who is serving or has served at the request of the Company as a director or executive officer of another company, joint venture, trust or other enterprise, including any the Company subsidiary (each, a covered person), against any expenses, including attorney s fees, judgments, fines, and amounts paid in settlement actually and reasonably incurred by him or her in connection with any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, to which he or she was, is, or is threatened to be made a party, or is otherwise involved (a proceeding), by reason of the fact that he or she is or was a covered person; *provided*, *however*, that this provision shall not indemnify any covered person against any liability arising out of (a) any fraud or dishonesty in the performance of such covered person s duty to the Company, or (b) such covered person s conscious, intentional or willful breach of the obligation to act honestly and in good faith with a view to the best interests of the Company. Furthermore, the directors, secretary and executive officers of the Company are expected to enter into indemnification agreements with the Company and/or one or more of its subsidiaries.

The foregoing summaries are qualified in their entirety to the terms and provisions of such arrangements.

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Item 16. ***Exhibits***

The exhibits to this Registration Statement are listed in the Exhibit Index to this Registration Statement, which Exhibit Index is hereby incorporated by reference.

Item 17. ***Undertakings***

The undersigned registrant hereby undertakes:

1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

   Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4) That, for the purpose of determining liability under the Securities Act to any purchaser:

   i. Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

   ii. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement

to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5) That, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report

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pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Toronto, Province of Ontario, Canada, on this 18th day of March, 2016.

Aralez Pharmaceuticals Inc.

By:	/s/ Adrian Adams	
	Name:	Adrian Adams
	Title:	Chief Executive Officer

BE IT KNOWN BY THESE PRESENTS: That each person whose name is signed hereto has made, constituted and appointed, and does hereby make, constitute and appoint Adrian Adams and Eric L. Trachtenberg, his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to affix his or her signature as director or officer or both, as the case may be, of the registrant, to any and all registration statements and amendments thereto (including post-effective amendments) and to file the same, with all exhibits thereto, and other documents in connection therewith, and to file with the SEC, granting unto each such attorney-in-fact full power and authority to do and perform every act and thing whatsoever necessary to be done in the premises, as fully as he or she might or could do if personally present, hereby ratifying and confirming all that each such attorney-in-fact shall lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated below.

Signature		**Title**	**Date**
By:	/s/ Adrian Adams Adrian Adams	Chief Executive Officer (Principal Executive Officer), Director	March 18, 2016
By:	/s/ Scott Charles Scott Charles	Chief Financial Officer (Principal Financial Officer)	March 18, 2016
By:	/s/ John E. Barnhardt John E. Barnhardt	Principal Accounting Officer	March 18, 2016
By:	/s/ Neal F. Fowler Neal F. Fowler	Director	March 18, 2016
By:	/s/ Arthur S. Kirsch Arthur S. Kirsch	Director	March 18, 2016
By:	/s/ Kenneth B. Lee, Jr. Kenneth B. Lee, Jr.	Director	March 18, 2016
By:	/s/ Seth A. Rudnick, M.D. Seth A. Rudnick, M.D.	Director	March 18, 2016
By:	/s/ Rob Harris Rob Harris	Director	March 18, 2016

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By:	/s/ Jason Aryeh Jason Aryeh	Director	March 18, 2016
By:	/s/ F. Martin Thrasher F. Martin Thrasher	Director	March 18, 2016

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INDEX TO EXHIBITS

Exhibit Number	Description
5.1	Opinion of DLA Piper (Canada) LLP (previously filed).
10.1	Amended and Restated Share Subscription Agreement, dated as of December 7, 2015, among Aralez Pharmaceuticals Inc., Aralez Pharmaceuticals plc, POZEN Inc., Tribute Pharmaceuticals Canada Inc., QLT Inc., Deerfield Private Design Fund III, L.P., Deerfield International Master Fund, L.P., Deerfield Partners, L.P., Broadfin Healthcare Master Fund Ltd., JW Partners, LP, JW Opportunities Fund, LLC, and JW Opportunities Master Fund, Ltd. (incorporated by reference to Exhibit 10.3 to POZEN Inc. s Current Report on Form 8-K filed December 8, 2015).
23.1	Consent of DLA Piper (Canada) LLP (included in Exhibit 5.1).
23.2	Consent of Ernst & Young LLP, independent registered public accounting firm.*
23.3	Consent of McGovern, Hurley, Cunningham, LLP, independent auditors for Tribute.*
24.1	Powers of Attorney (included on signature page to this Registration Statement).*

* Filed herewith.

+ Certain disclosure schedules have been omitted. Aralez hereby agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.