AQUINOX PHARMACEUTICALS, INC
Form 10-K
March 16, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

OR

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

For the transition period from_____ to _____

Commission file number: 001-36327

Aquinox Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**98-0542593**
(State or other Jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

450-887 Great Northern Way,

Vancouver, B.C., Canada V5T 4T5

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: (604) 629-9223

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

Title of class	**Name of each exchange on which registered**
Common Stock, par value $0.000001	**The NASDAQ Stock Market LLC**

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

None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $41,572,146 as of the last business day of the registrant s most recently completed second fiscal quarter, based upon the closing sale price on The NASDAQ Global Market reported for such date. Excludes an aggregate of 6,286,523 shares of the registrant s common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

There were 10,717,128 shares of the registrant s Common Stock issued and outstanding as of March 12, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant s 2015 Annual Meeting of Stockholders (the ***2015 Proxy Statement***).

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AQUINOX PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2014

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Except as otherwise indicated herein or as the context otherwise requires, references in this report to Aquinox, the company, we, us, our and similar references refer to Aquinox Pharmaceuticals, Inc., a Delaware corporation, which we refer to in this report as Aquinox USA, and Aquinox Pharmaceuticals (Canada) Inc., a corporation under the Canada Business Corporations Act and a wholly owned subsidiary of Aquinox USA, which we refer to in this report as AQXP Canada. This report contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Business.

Overview

We are a clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. Our primary focus is anti-inflammatory product candidates targeting SHIP1, which is a key regulator of an important cellular signaling pathway in immune cells, known as the PI3K pathway. Our lead product candidate, AQX-1125, is a small molecule activator of SHIP1 suitable for oral, once daily dosing. Having successfully completed multiple preclinical studies and clinical trials with AQX-1125, we are now advancing through Phase 2 development in several initial indications. We have successfully completed three clinical trials with AQX-1125 dosed as a once daily oral product, with over 100 subjects having received AQX-1125 to date. We are currently investigating AQX-1125 in three Phase 2 clinical trials, one in Chronic Obstructive Pulmonary Disease (COPD), one in Bladder Pain Syndrome/Interstitial Cystitis (BPS/IC), and one in Atopic Dermatitis (AD). COPD, BPS/IC and severe forms of AD are debilitating chronic inflammatory diseases affecting millions of people worldwide.

Inflammation may be reduced by activation of SHIP1, a natural modulator of the PI3K pathway. If the PI3K pathway is overactive, immune cells often produce an abundance of pro-inflammatory signaling molecules which migrate to and concentrate in tissues, resulting in excessive or chronic inflammation. Drugs activating SHIP1 may reduce the function and migration of immune cells and have an anti-inflammatory effect. In addition, because SHIP1 is predominantly present in immune cells, off-tissue toxicities may be minimized. Immune cells with lowered levels of SHIP1 cause abnormal inflammation at mucosal surfaces in response to inflammatory stimuli. Accordingly, we are targeting inflammatory diseases that occur at the skin and at mucosal surfaces, including those of the respiratory, urinary and gastrointestinal tracts, for which we believe there is broad therapeutic and market potential.

Our longer-term strategy is to broaden our development activities for AQX-1125 and to advance next generation SHIP1 activators for the treatment of additional inflammatory diseases and cancer.

SHIP1 and the PI3K Pathway

Role and Regulation of the PI3K Pathway

The PI3K pathway is a cellular signaling pathway that has been linked to a diverse group of cellular functions and biological processes such as cell activation and migration, which are related to inflammation, and cell growth, proliferation and survival, which are related to cancer. As a result, the PI3K pathway is heavily researched by the academic community as well as pharmaceutical and biotechnology companies in the areas of immune disorders and cancer.

In the PI3K pathway, the key messenger molecule is phosphatidylinositiol-3,4,5-trisphosphate, or PIP3, which initiates the signaling pathway. In cells derived from bone marrow tissues (e.g. immune cells), the key enzymes that control levels of PIP3 are the PI3 kinase, or PI3K, and the phosphatases, phosphatase and tensin homolog, or PTEN, and SH2-containing inositol-5 -phosphatase 1, or SHIP1. PI3K generates PIP3, thus initiating the signaling pathway. This signaling is reduced by degradation of PIP3 by PTEN and SHIP1. PTEN is generally considered to be constantly working in the pathway, whereas SHIP1 is activated when the cell is stimulated. In preclinical studies, PTEN has been shown to suppress cancer by controlling cell proliferation, whereas SHIP1, when functioning, has been demonstrated to control inflammation by reducing cell migration and activation.

If the PI3K pathway is overactive, immune cells can produce an abundance of pro-inflammatory signaling molecules and migrate to and concentrate in tissues, resulting in excessive or chronic inflammation. SHIP1 is predominantly expressed in cells derived from bone marrow tissues, which are mainly immune cells. Consequently, drugs that activate SHIP1 can reduce the function and migration of immune cells and have an anti-inflammatory effect.

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SHIP1 as a Drug Target

Inflammation can be reduced by activation of SHIP1, taking advantage of the natural modulation of the PI3K pathway. When activated, SHIP1 redirects signaling in immune cells to reduce their activation and migration, thereby reducing inflammation while still allowing these cells to maintain cell growth and survival. Our scientific founders, based at the University of British Columbia, were the first to discover SHIP1 and show that small molecules could activate it, thereby making it a potential target for a new class of anti-inflammatory drugs. Additionally, academic scientists have shown that certain immune cell cancers have suppressed levels of SHIP1, making such cancers also potential targets for SHIP1 activators.

SHIP1 is predominantly present in immune cells. Therefore, SHIP1 activators target immune cells to cause an anti-inflammatory effect while minimizing effects in other tissues. We believe AQX-1125 is the only SHIP1 activator currently in clinical trials and that no SHIP1 activator has yet received marketing approval as a treatment for disease in humans.

Our approach also targets a unique activation site in SHIP1 called the C2 binding domain. We have demonstrated that targeting the C2 binding domain does not significantly activate or inhibit other enzymes, imparting target selectivity and further limiting potential off-target toxicities. Historically, phosphatases such as SHIP1 have been found to be poor drug targets based upon efforts to develop inhibitors of these enzymes, since the binding sites for inhibitors are similar across the family of phosphatases, resulting in poor selectivity and leading to undesired off-target toxicities. The unique activation site of SHIP1 enables this important phosphatase as a drug target.

The SHIP1 Knockout Mouse Provides a Roadmap for Clinical Development

Our scientific founders developed a strain of genetically modified mouse, which we refer to as the SHIP1 knockout mouse, with an immune system that lacks the presence of SHIP1. This SHIP1 knockout mouse has been useful for determining which diseases develop when the PI3K pathway is unregulated by SHIP1. A SHIP1 knockout mouse is viable and fertile and does not exhibit abnormal inflammation if raised under sterile conditions. However, if exposed to environmental inflammatory challenges like allergens or bacteria, a SHIP1 knockout mouse develops severe progressive inflammation and fibrosis of its airways, similar to respiratory diseases seen in humans. In addition, a SHIP1 knockout mouse, when exposed, develops inflammation of the urinary bladder, and gastrointestinal lining.

Abnormal inflammation observed in a SHIP1 knockout mouse occurs at mucosal surfaces, including those of the respiratory, urinary and, gastrointestinal linings. These surfaces are important barriers between the body and the external environment. Chronic inflammation at the surfaces of the body, such as the skin and mucosal surfaces, reduces the effectiveness of these barriers and may lead to a variety of diseases.

Potential Clinical Indications

Given our findings with respect to the SHIP1 knockout mouse, we are focused on diseases characterized by inflammation at the surfaces of the body. There is a broad range of diseases characterized by inflammation of the body s surfaces and we believe there is broad therapeutic and market potential for drugs that can activate SHIP1. Inflammatory diseases of the mucosal surfaces of the respiratory, urinary and gastrointestinal tracts are increasing worldwide in both number and incidence. In addition, we are exploring inflammatory diseases of the skin, which shares similar properties to that of mucosal surfaces and is a large barrier to the environment by surface area.

A number of diseases are characterized by skin or mucosal inflammation including:

Lung/Airway

Moderate-Severe COPD

Chronic Sinusitis

Severe Asthma

Non-CF Bronchiectasis

Churg-Strauss Syndrome

Idiopathic Pulmonary Fibrosis

Urinary Tract

BPS/IC

Glomerulonephritis

Gastrointestinal Tract

Eosinophilic Esophagitis

Crohn s Disease

Ulcerative Colitis

Skin

Moderate-Severe Atopic Dermatitis

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We are currently conducting three Phase 2 clinical trials, one in COPD, one in BPS/IC and one in AD. In the future, we expect to expand our clinical development into other inflammatory diseases. We have selected these initial indications based on the following criteria:

- large patient populations with generally inadequate therapy to facilitate rapid enrollment in clinical trials;
- an attractive commercial opportunity with limited competition; and
- an acute phase of the disease or an endpoint that could reasonably be affected in three months of treatment.

Our Discovery Platform

We believe our discovery platform enables us to discover new drug candidates that selectively target SHIP1 to modulate activated immune cells while minimizing their toxicity to normal cells. Our discovery platform includes:

- a novel *in vitro*, high throughput assay to screen SHIP1 activators;
- a patented approach to screening drugs against the C2 binding domain;
- the use of the SHIP1 knockout mouse to produce cells for *in vitro* experiments or for *in vivo* studies to determine the selectivity and specificity of our compounds; and
- an extensive library of chemical compounds that are known to be SHIP1 activators.

Our discovery platform was initially applied to the screening of a natural product library of compounds to identify potential SHIP1 activators, which SHIP1 activators were covered by an exclusive license from the University of British Columbia. We chemically modified these initial compounds to improve their activity and pharmaceutical properties, which resulted in several classes of SHIP1 activator compounds being developed. From these compound classes, we developed a key understanding of the chemical structured characteristics of SHIP1 activators. With this understanding of what compounds activate SHIP1 and their chemical structures, we identified additional compound classes in other libraries of interest. We acquired one proprietary compound library of interest from Biolipox AB, with all patents transferred to us without any future royalty obligations. We screened compounds from this acquired library and confirmed that it contained SHIP1 activators, including a compound that was the basis for AQX-1125.

Our Pipeline

AQX-1125 is our clinical-stage product candidate. In addition, we have several other pre-clinical candidates that also target SHIP1 and that have both similar and distinct properties from AQX-1125, with some showing preliminary evidence of enhanced anti-inflammatory and anti-cancer properties.

The development status of AQX-1125 and our next generation product candidates is summarized below:

AQX-1125

AQX-1125 is our lead product candidate and has generated positive clinical data from three completed clinical trials, including two proof-of-concept trials, one in COPD and one in allergic asthma, demonstrating a favorable safety profile and anti-inflammatory activity. Importantly, our clinical trial results were consistent with the pharmaceutical properties and anti-inflammatory activities demonstrated in our preclinical studies. AQX-1125 is a once daily oral capsule with many desirable pharmaceutical properties. We are currently investigating AQX-1125 in three Phase 2 clinical trials, one in COPD, one in BPS/IC and one in AD. For AQX-1125, we retain full worldwide rights and hold patents with terms through at least 2024.

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AQX-1125 Activates SHIP1, Reducing Inflammation

AQX-1125 is an activator of SHIP1, which controls the PI3K cellular signaling pathway. If the PI3K pathway is overactive, immune cells can produce an abundance of pro-inflammatory signaling molecules and the cells migrate to and concentrate in tissues, resulting in excessive or chronic inflammation. SHIP1 is predominantly expressed in cells derived from bone marrow tissues, which are mainly immune cells. Therefore drugs that activate SHIP1 can reduce the function and migration of immune cells and have an anti-inflammatory effect. By controlling the PI3K pathway, AQX-1125 reduces immune cell function and migration by targeting a mechanism that has evolved in nature to maintain homeostasis of the immune system.

AQX-1125 has Desirable Pharmaceutical Properties

In addition to demonstrating strong *in vitro* and *in vivo* activity, AQX-1125 was also selected as a lead candidate based on its many desirable pharmaceutical properties. It is highly water-soluble and does not require complex formulation for oral administration. AQX-1125 has low plasma protein binding, is not metabolized and is excreted un-metabolized in both urine and feces. After oral or intravenous dosing, AQX-1125 reaches high concentrations in respiratory, urinary, and gastrointestinal tracts, all of which have mucosal surfaces of therapeutic interest. In humans, AQX-1125 has shown pharmacokinetic properties suitable for once-a-day dosing. In addition, the absorption of the drug candidate is equivalent whether taken with or without food.

AQX-1125 is Active in a Broad Range of Preclinical Inflammatory Studies

We have demonstrated compelling preclinical activity in a broad range of relevant inflammatory studies including preclinical models of COPD, asthma, pulmonary fibrosis, BPS/IC, AD, and inflammatory bowel disease (IBD). In these studies we have seen a meaningful reduction in the relevant immune cells that are the cells that cause inflammation, such as neutrophils, eosinophils and macrophages, and a reduction in the symptoms of inflammation, such as pain and swelling. The following table summarizes these supportive results from our preclinical *in vivo* studies with AQX-1125:

CLINICAL INDICATION	ANIMAL MODEL	PRIMARY ENDPOINT
COPD/Respiratory	LPS Airway Inflammation (Rat)	Reduction of neutrophils
	Ovalbumin Airway Inflammation (Rat)	Reduction of eosinophils
	Smoke Airway Inflammation (Mouse)	Reduction of neutrophils
	Bleomycin Fibrosis (Mouse)	Reduction of fibrosis and increase in survival
BPS/IC	Cyclophosphamide Bladder Cystitis (Rat)	Reduction of inflammation, pain and hemorrhage
	Carrageenan Paw Edema (Mouse)	Reduction of edema
IBD	TNBS IBD (Rat)	Reduction of adhesions/strictures and inflammation
AD	Passive Cutaneous Anaphylaxis (Mouse)	Reduction of edema
	Phorbol Myristate Acetate (Mouse)	Reduction of edema and neutrophil recruitment

Carrageenan Paw Edema (Mouse)	Reduction of edema
Psoriasis (Mouse)	Reduction of erythema and scaling

The activity, efficacy and potency seen with AQX-1125 in preclinical studies compare favorably to published results with corticosteroids. In addition, AQX-1125 demonstrated compelling activity in the smoke airway inflammation and bleomycin fibrosis models, which are known to be steroid refractory (i.e., do not respond to corticosteroids). We believe this broad anti-inflammatory profile is not typical among other drugs in development and supports the therapeutic potential and continued development of AQX-1125.

AQX-1125 has Demonstrated Desirable Properties in Three Completed Clinical trials

Overall, more than 100 subjects have received AQX-1125 in three separate completed trials. An overview of these clinical trials is described below.

Phase 1 Safety Trial

We conducted a Phase 1, three-part, randomized, placebo-controlled, dose escalation trial of the safety, tolerability, pharmacokinetics and food effect of AQX-1125 in normal healthy subjects. This trial investigated single doses of AQX-1125 ranging from 17 mg to 542 mg (single ascending dose, or SAD, part, n = 16), daily doses ranging from 100 mg to 542 mg for up to ten days (multiple ascending dose, or MAD, part, n = 18) and daily dose of 200 mg for seven days in fasted or fed subjects (food effect part, n = 12).

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In the SAD part of our Phase 1 trial, AQX-1125 demonstrated desirable pharmaceutical properties: it is rapidly and nearly completely absorbed; it has dose proportional pharmacokinetics; and it has a consistent plasma half-life of approximately 21 hours. The results of the SAD part of our Phase 1 trial are shown below.

From a safety perspective, there were no drug-related adverse events reported in the SAD part.

In the MAD part of our Phase 1 trial, which studied AQX-1125 for ten days, AQX-1125 reached steady state levels after the first four days of dosing and again had dose proportional pharmacokinetics and a consistent half-life. The results of the MAD part of our Phase 1 trial are shown below.

The most frequently reported drug-related and dose-related adverse events in the MAD part were related to gastrointestinal upset. All other adverse events were at a similar level to those reported with placebo. All adverse events were short-lived, observed in the first seven days of dosing, and resolved without treatment or long-term effects. Based on these data, treatment with single daily doses of either 100 mg, 250 mg or 542 mg AQX-1125 for ten days was generally well tolerated in healthy subjects. The maximum tolerated dose was considered not to be reached. In the food effect part of the trial, the absorption of the drug was considered equivalent whether taken with or without food.

The Phase 1 safety trial demonstrated that AQX-1125 has many desirable pharmaceutical properties. The consistent pharmacokinetics and safety profile of AQX-1125, combined with its high level of bioavailability, low protein binding and lack of metabolism, contribute to the consistent results to date from subject to subject, which we believe are positive attributes for future clinical trials and commercialization.

Following the completion of the Phase 1 safety trial, we initiated two proof-of-concept clinical trials of inflammation to demonstrate the first evidence of AQX-1125 activity, and importance of SHIP1 as a target, in humans.

Phase 1b COPD Proof-of-Concept Trial

The first proof-of-concept trial was conducted to evaluate the anti-inflammatory properties, safety and pharmacokinetics of AQX-1125 following a lipopolysaccharide (LPS) challenge in healthy subjects. In the LPS challenge, patients inhale aerosolized LPS which induces an acute inflammatory response that is characterized by the activation and migration of neutrophils into the lung and results in a mild, transient and fully reversible impairment in pulmonary function. The inflammatory response induced by LPS inhalation (in

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healthy volunteers) is considered a model of the inflammatory mechanisms seen in patients with COPD. This type of proof-of-concept trial has been undertaken by other pharmaceutical companies to evaluate other anti-inflammatory therapies for COPD. This type of trial needs to be conducted in healthy volunteers whose normal lungs can tolerate the inflammatory response to LPS, as exposing COPD patients to LPS could induce a dangerous exacerbation.

Our trial was designed to investigate two doses of AQX-1125, 450 mg and 200 mg, in a placebo controlled crossover format where each subject received either drug for seven days, followed by placebo for seven days, or vice versa. The 450 mg part of the trial was successfully completed. Following seven days of once-daily treatment with 450 mg AQX-1125 or placebo, subjects (n = 18) were challenged with 50 µg of LPS at two hours following the last dose on day seven. AQX-1125 met its primary endpoint in the 450 mg dose part by reducing sputum neutrophils by approximately 62% (p=0.062) compared to placebo. AQX-1125 also showed a reduction in sputum IL-6 and, although not statistically significant, showed a trend towards a reduction in sputum IL-8, both of which are important cytokines in the activation and recruitment of neutrophils. In addition to the effects on neutrophils and cytokines, a trend towards reduction in other immune cells in sputum, namely eosinophils and macrophages, was also observed. The reduction of sputum neutrophil levels compares favorably to published results for anti-inflammatory drugs that are in development, or have been approved, for the treatment of COPD. The results of the 450 mg dose part of our trial are shown below.

The results of the 200 mg dose (n = 18) part of the trial were limited to safety and pharmacokinetic measurements. Due to a technical processing error at a third-party laboratory, we were unable to measure the magnitude of sputum neutrophil inhibition.

Reported adverse events were mild to moderate, with the majority being similar to reports from other published LPS challenge trials and relate to the administration of LPS (e.g., fever, chills, malaise, cough, chest tightness, headache and muscle pain). The most frequently reported dose-related adverse event was gastrointestinal upset. All adverse events resolved without treatment or long-term effects.

The results for AQX-1125 compare favorably with published results for other oral drugs studied in similar LPS challenge trials that either are in development or have been approved for the treatment of COPD. This proof-of-concept trial supported further development of AQX-1125 in COPD.

Phase 2a Allergic Asthma Inflammation Proof-of-Concept Trial

The second proof-of-concept trial evaluated the anti-inflammatory properties, safety and pharmacokinetics of AQX-1125 following an inhaled allergen challenge in mild to moderate asthmatics. Allergen, when inhaled, is a pro-inflammatory stimulus and in general can be used to evaluate the effects of anti-inflammatory compounds on allergic inflammation. Following inhalation of allergen, asthmatics develop an acute asthmatic attack which peaks at 20 to 30 minutes. Even if initially treated with bronchodilators, approximately 50% of these subjects develop secondary airway inflammation, known as the late asthmatic response (LAR), between four and ten hours after inhalation. This type of proof-of-concept trial has been undertaken by other pharmaceutical companies to evaluate the ability of other anti-inflammatory therapies to prevent or reduce the LAR.

AQX-1125 (450 mg) was investigated in a randomized, double-blind, placebo-controlled crossover format. Steroid-naïve asthmatics (n = 22) were randomized to AQX-1125 followed by placebo, or to placebo followed by AQX-1125, for seven days each. The primary efficacy measure was the LAR as measured by the forced expiratory

volume in one second (FEV_1) from four to ten hours after allergen challenge (AUC_{4-10}). The trial met its primary endpoint by demonstrating an approximate 20% improvement in the LAR by 450 mg of AQX-1125 versus placebo ($p = 0.027$) and although not statistically significant, a reduction in all immune cells that were measured in sputum.

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All of the adverse events reported in the trial were mild to moderate, with the most frequently reported being headaches and gastrointestinal upset. All adverse events resolved without treatment or long-term effects.

The results for AQX-1125 compare favorably with published results for other drugs studied in similar allergic challenge trials that are either in development or that have been approved. More importantly, this proof-of-concept trial provides evidence of the ability of AQX-1125 to modulate allergic responses at a mucosal surface after exposure to an allergen. We believe this may imply usefulness for AQX-1125 in a range of diseases characterized by allergic inflammation such as chronic sinusitis, eosinophilic esophagitis and diseases that may have an allergic component, such as BPS/IC and AD.

AQX-1125 Safety Profile

Safety data have been obtained from over 100 subjects from our three completed trials who have been exposed to doses of AQX-1125 ranging from 17 mg to 542 mg for up to ten consecutive days. All of the treatment-related adverse events reported to date in the completed trials have been mild to moderate in intensity, and there have been no deaths, no withdrawals due to treatment-related adverse events and no serious adverse events or suspected unexpected serious adverse events (SUSAR) reported.

In addition, there have been no drug-related, clinically significant, adverse changes in any laboratory parameter in the completed trials. The most frequent dose-related adverse event that increased with increasing dose was gastrointestinal disorder, which was intermittent and resolved without treatment or long-term effects. Frequency of gastrointestinal adverse events decreased with lower dose and with reduced fasting time, consistent with the adverse events being associated with irritation of the gastrointestinal lining from the rapid dissolution and absorption of AQX-1125. For the current and future trials, AQX-1125 will be administered with food with the goal of avoiding gastrointestinal events. The adverse events noted for AQX-1125 have been consistent across all trials completed to date.

Clinical Trial Summary

Based on our three completed clinical trials, we have demonstrated that AQX-1125:

- has desirable pharmacokinetic, absorption and excretion properties that make it suitable for once daily oral administration;
- is generally well tolerated, exhibiting mild to moderate adverse events primarily related to gastrointestinal upset that resolve without treatment or long-term effects and are reduced by taking the drug candidate with food; and
- has anti-inflammatory properties consistent with those exhibited in preclinical studies and exhibited activity in two trials using two distinct inflammatory challenges.

Development Plan

Based upon the supportive preclinical and clinical data generated to date, we have advanced AQX-1125 to three Phase 2 trials. In general, the factors we considered most important in selecting our Phase 2 trials were:

large patient populations with generally inadequate current therapy;

an attractive commercial opportunity with limited competition; and

an acute phase of the disease or an endpoint that could reasonably be affected in three months of treatment.

While we believe there is an expansive list of potential clinical indications that could potentially benefit from treatment with AQX-1125, we selected COPD, BPS/IC and AD for further Phase 2 evaluation based on the preceding factors.

Dose Selection for Phase 2

We selected 200 mg once daily as the most appropriate dose for our Phase 2 COPD, BPS/IC and AD trials based upon preclinical efficacy/target coverage experiments, regulatory considerations and human dosing/activity results from Phase 1 and 2a. Human doses as low as 70 mg daily would provide blood levels of AQX-1125 equal to or greater than the average blood levels needed to achieve maximum efficacy in animal models. From our preclinical pharmacodynamic/pharmacokinetic (PK/PD) studies the observed maximal efficacy occurs in animal models at an average plasma concentration of 90 ng/ml (40-140 ng/ml). We believe 200 mg daily will provide excess target coverage (281 ng/ml) and an appropriate safety margin for extended duration dosing (e.g. six weeks or greater in current Phase 2 trials). From a safety perspective, in our completed trials a 200 mg dose was demonstrated to have a side effect profile equivalent to placebo and the plasma drug concentration in humans at this dose corresponds with a dose in animals that caused no toxicity for up to 13 weeks. We expect that future development of AQX-1125 will include clinical trials that will explore lower doses of AQX-1125, as establishing the minimally effective dose is an important endpoint for drugs that are intended for extended or chronic dosing.

Chronic Obstructive Pulmonary Disease

COPD is a lung disease frequently associated with cigarette smoking and air pollution. COPD is characterized by progressive loss of lung function and chronic inflammation of the airways. The disease is estimated to affect up to 600 million people worldwide with estimates of the number of people suffering from the moderate and severe forms that most frequently require treatment ranging from 65 million to over 200 million. It is the third leading cause of death in the United States and worldwide. COPD affects almost 25 million people in the United States alone, at an estimated annual economic burden of $50 billion. COPD is the leading cause of urgent hospitalization in developed countries.

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COPD Exacerbations COPD patients suffer periodic episodes with severe worsening of symptoms, known as exacerbations. Exacerbations are characterized by severe airway inflammation triggered by various factors, such as viral or bacterial infection, or environmental irritants. Symptoms include cough, difficulty breathing, elevated mucous production, reduced tolerance to exertion and fatigue, and these symptoms typically worsen over time and often cause feelings of suffocation, panic and anxiety. Exacerbations can be so severe that they lead to respiratory failure and death. These exacerbations have a profoundly negative impact on the quality of life and long-term survival of patients and cause significant challenges for healthcare systems and the global economy. Each year, on average, COPD patients experience one or two exacerbations, which may be classified as mild, moderate or severe (requiring hospitalization). Of COPD patients, 22-40% die within one year of a severe exacerbation and 66% die within three years. Since exacerbations involve severe increased airway inflammation, treatment with potent anti-inflammatories that reduces the recruitment of immune cells (especially neutrophils) to the lungs is a potentially promising strategy to reduce exacerbations.

A 2009 study by Hurst, et al, of COPD patients demonstrated that there are generally two categories of patients with COPD exacerbations: those with infrequent exacerbations (stable) and those with frequent exacerbations (unstable). This was the first study to document the major finding that in unstable patients, exacerbations tend to cluster together; therefore patients that have had an exacerbation are at highest risk of having secondary exacerbations within the next eight weeks. The unstable COPD patients tend to have clusters of exacerbations on an annual basis, often having a second or even third exacerbation within eight to 12 weeks of their first. The study reported that approximately 27% of patients on study had a second, discrete exacerbation within eight weeks of their most recent exacerbation. This is consistent with a United Kingdom national audit of COPD outcomes, in which 34% of 1,221 hospitalized patients with exacerbations of COPD were readmitted in the subsequent three months. In contrast, the stable COPD population is characterized by effective treatment and resolution of their first exacerbation and typically no further worsening of their symptoms for at least 12 weeks.

A medical editorial that reviewed the results of the Hurst study suggested that it may be of particular importance, regardless of exacerbation frequency, to target patients after an initial exacerbation. It would be clinically important to prevent a second exacerbation in a COPD patient who has had a recent first exacerbation. However, clinical trials to date with preventive medications have, by virtue of their exclusion criteria, not addressed this issue. Most COPD clinical trials with bronchodilators, either alone or in combination with inhaled corticosteroids, have intentionally excluded patients that experienced a recent COPD exacerbation. The data presented by Hurst and colleagues suggest that this is an incorrect approach, because it is these very patients who are most at risk for recurrent exacerbations and who can be expected to drive clinical trial outcomes. We believe that a trial design that intentionally enrolls patients that have experienced a recent exacerbation to prevent a recurrent exacerbation represents an important opportunity for anti-inflammatory therapy.

COPD Current Therapy Most marketed therapies for COPD are inhaled drugs directed towards managing symptoms by dilating narrowed airways (bronchodilators) often in combination with inhaled corticosteroids intended to open the airways to improve the ease of breathing. These inhaled therapies have modest effects on slowing the progression of COPD or reducing exacerbations. With over two decades of innovation and incremental improvement from new bronchodilator approvals, the majority of moderate and severe COPD patients still suffer from periodic exacerbations and approximately two-thirds of these patients have multiple exacerbations per year. The scientific literature also questions the value of inhaled corticosteroids in the treatment of COPD and links their use to increased risk of pneumonia and yeast infections of the mouth and throat.

The standard treatment following an exacerbation is a combination of antibiotics and/or oral corticosteroids, both of which can only be used for short durations typically ten to 14 days due to toxicities or risk of resistance from prolonged use. Following treatment and withdrawal from oral corticosteroids, unstable COPD patients frequently have

a re-emergence of exacerbation symptoms within a two-month period that can lead to hospitalization or urgent care.

The recently approved phosphodiesterase-4 or PDE4 inhibitor, roflumilast (Daliresp), for the treatment of severe COPD associated with chronic bronchitis, is the only approved oral therapy indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Roflumilast has demonstrated some ability in reducing exacerbations but its clinical use is limited due to its side effect profile. Despite their limitations and restricted use, the evidence that both oral corticosteroids and roflumilast can reduce and treat exacerbations provide the precedent that oral anti-inflammatory therapy is an important strategy for improving the management of COPD. We believe that there is a significant medical need for new oral therapies to treat the acute and chronic lung inflammation that COPD patients experience, to reduce the severity, duration and reoccurrence of exacerbations and to slow or prevent disease progression. We believe that the anti-inflammatory properties that we have observed for AQX-1125 to date compare favorably with roflumilast and oral corticosteroids while having a safety profile potentially more suitable for prolonged use.

The Flagship Trial: AQX-1125 in COPD Patients with Frequent Exacerbations Our Phase 2 trial, known as the Flagship trial, is evaluating the effect of AQX-1125 compared to placebo in approximately 400 unstable moderate to severe COPD patients who have experienced a recent exacerbation and at least two other exacerbations in the prior 18 months. We believe this trial targets the COPD patients in greatest need and with the highest likelihood of responding to anti-inflammatory therapy. Enrolling patients who are expected to have frequent exacerbations permits the trial design to allow fewer patients and shorter required dosing to see a positive outcome compared to historical trials of bronchodilators. The trial is sized to detect a significant change in the primary

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endpoint of the change in the severity, duration and reoccurrence of exacerbations in patients treated with AQX-1125 versus placebo, as measured by EXACT-PRO, a patient-reported tool that measures symptoms. We are evaluating AQX-1125 administered as once daily oral 200 mg capsules for 12 weeks in this multi-center, randomized, double-blind, placebo-controlled Phase 2 trial to reduce the severity, duration and reoccurrence of exacerbations on top of standard of care. This trial is being conducted in Northern and Central Europe, Australia, New Zealand, and the United States. The Flagship trial is being conducted in hospitals, outpatient clinics and research units and has completed enrollment of 400 patients. Top-line data is expected near mid-year 2015. COPD patients were randomized to receive either AQX-1125 or placebo in addition to the current standard of care. Full results are expected to be submitted for publication and presented at a leading medical conference. If positive results in this trial are achieved, we intend to meet with the FDA and other regulatory authorities to determine the most appropriate path to marketing approval for AQX-1125.

We believe the selection of COPD as a targeted clinical indication matches well with the demonstrated ability of AQX-1125, in both preclinical studies and clinical trials, to reduce inflammation, in particular neutrophils, in the airways in response to environmental inflammatory stimuli. The trial includes COPD patients with frequent exacerbations. This allows for shorter trial duration and reduced number of patients needed to see sufficient clinical events to detect the effects of AQX-1125 in a 12-week trial. This novel trial design utilizes the recently developed EXACT-PRO measurement tool, which is a highly sensitive patient reported questionnaire utilizing electronic diaries for accurate and reliable capture of data on the daily symptoms affecting COPD patients.

The EXAcerbations of Chronic pulmonary disease Tool (EXACT), a patient-reported outcome (PRO), or EXACT-PRO, is a recent development for research of exacerbations in COPD patients. EXACT-PRO was designed to standardize the method for evaluating the frequency, severity and duration of exacerbations. The EXACT-PRO initiative was spearheaded by United Biosource Corporation, an Express Scripts Company, with input from the FDA and was funded by a consortium of pharmaceutical companies, including AstraZeneca plc, Almirall S.A., Bayer AG, Bohringer Ingleheim Corporation, Forest Pharmaceuticals, Inc., GlaxoSmithKline plc, Merck & Co., Inc., Novartis AG, Ortho-McNeil Pharmaceutical, a division of Johnson & Johnson, Pfizer, Inc. and Sunovion Pharmaceuticals, Inc. It is available in more than 40 languages and has been tested in a number of validation studies in approximately 50 countries, with a comprehensive evidence dossier submitted to the FDA and EMA for qualification of this tool for use in Phase 3 trials.

EXACT-PRO provides data and quantification of numerous symptoms on a daily basis, thereby providing more robust and continuous measure of the effects of AQX-1125 on COPD exacerbations. We believe EXACT scores may be particularly useful in studying an exacerbation patient s recovery pattern, allowing a more sensitive measure of a patient s progress, rather than simply whether a patient has experienced another exacerbation or deteriorated to the point where the patient requires hospitalization, which was a typical endpoint prior to the development of EXACT-PRO. We are not aware of any other clinical trial utilizing EXACT scores as a primary endpoint in a Phase 2 or Phase 3 trial conducted over 12 weeks or longer. The FDA has accepted our IND application for the Flagship trial and we shared the use of EXACT-PRO as our primary endpoint for this trial; however, we do not know whether the FDA will accept EXACT-PRO as a primary endpoint for Phase 3 trials instead of more traditional COPD trial endpoints. Overall, we believe that we will collect substantially more data by using EXACT-PRO compared to traditional COPD trial endpoints that will be beneficial in guiding our marketing approval strategy for AQX-1125.

Bladder Pain Syndrome/Interstitial Cystitis

BPS/IC is a chronic urinary bladder disease characterized by erosion of the lining and chronic inflammation of the bladder, pelvic pain and increased urinary urgency and/or frequency. Stress or a change in diet has been known to trigger BPS/IC symptoms. BPS/IC affects men and women of all ages. BPS/IC currently affects an estimated

14 million people in the United States and is accepted to be one of the most challenging urological conditions without effective therapy.

Chronic inflammation within the bladder wall can lead to damage and fibrotic changes in the bladder. There have been several studies linking allergic sensitivity to worsening BPS/IC symptoms. Furthermore, the inflammation leads to the release of mediators that irritate and trigger surrounding nerve tissue and causes radiating pain. For many BPS/IC sufferers, their symptoms of constant pain and urinary frequency are severe and adversely affect all major aspects of their lives, including overall physical and emotional health, employment, social and intimate relationships, and leisure activities.

The diagnosis of BPS/IC is often challenging and is based on exclusion of other diseases, including bladder cancer, kidney stones, vaginitis, endometriosis, sexually transmitted diseases and prostate infections. BPS/IC is generally diagnosed through cystoscopy or hydrodistention under anesthesia; however, many cases are overlooked. Sometimes patients have to see a number of doctors and specialists over a period of several years to obtain a correct diagnosis.

BPS/IC Current Therapies There is no known cure for BPS/IC, although a number of therapies can relieve symptoms. The only approved oral therapy is an agent, pentosan polysulfate (Elmiron), first approved in 1996, which helps to temporarily restore the bladder lining. Other therapies include such approaches as antihistamines, low dose antidepressants to fight neurogenic pain and analgesics. Most BPS/IC patients continue to suffer this debilitating condition, despite treatment with existing therapies. Most current therapies and those in development are focused solely on symptomatic relief of BPS/IC.

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In addition to oral therapies, direct instillation of drugs into the bladder via catheter (intravesical therapy) has been shown to provide temporary relief of symptoms. Dimethylsulfoxide (DMSO; RIMSO-50) is the only drug approved by the FDA for bladder instillation for BPS/IC. It offers anti-inflammatory, muscle relaxant and analgesic effects. DMSO is used alone or in combination with heparin, corticosteroids, bicarbonate and a local anesthetic (lidocaine) for intravesical administration.

Corticosteroids have also been reported to work via transurethral injection into the bladder wall or instillation into the bladder. Prolonged use of corticosteroids by BPS/IC patients is associated with bladder wall scarring. The American Urological Association guidelines for BPS/IC specifically state that corticosteroids are not recommended and should be avoided for chronic treatment of BPS/IC. Nonetheless, there is supporting evidence that achieving sufficient concentration of an anti-inflammatory compound in the bladder can reduce the pain and urinary symptoms associated with BPS/IC.

Instillation therapies are invasive and inconvenient, and oral therapies can offer significant potential advantages for BPS/IC patients. However, despite precedents for BPS/IC anti-inflammatory therapies, there are no satisfactory oral therapies currently available. We believe there is a significant medical need for new and innovative treatments that target the underlying inflammatory disease process.

The Leadership Trial: AQX-1125 in BPS/IC patients Our Phase 2 trial, known as the Leadership trial, is investigating the ability of AQX-1125, compared to placebo, to reduce pain and urinary symptoms in approximately 70 BPS/IC patients. We believe AQX-1125 is a candidate for evaluation in BPS/IC due to the fact that it has demonstrated activity in both preclinical studies and clinical trials relevant to BPS/IC, is delivered to the bladder via the bloodstream, and in pre-clinical studies, is eliminated, unmetabolized, into the urine, thereby achieving high concentrations proximate to the inflamed bladder wall. The Leadership trial is a multi-center randomized, double-blind, placebo-controlled Phase 2 trial of AQX-1125 once daily oral 200 mg capsules for six weeks in women suffering from chronic pain associated with BPS/IC. The trial is sized to detect a statistically significant change in the primary endpoint of the difference in the change from baseline in the mean daily bladder pain score based on an 11-point numeric rating scale at two, four and six weeks recorded by electronic diary. We have now completed enrolment for the Leadership trial. With 69 patients randomized to date and a higher completion rate than forecast for the trial, we have met our enrolment objectives. Top-line data is expected near mid-year 2015. Full results are expected to be submitted for publication and presented at a leading medical conference. If positive results are achieved in this trial, we intend to meet with the FDA and other regulatory authorities to determine the most appropriate path to marketing approval for AQX-1125.

We believe that we have incorporated strategies into our Phase 2 trial for AQX-1125 in BPS/IC that address the shortcomings of prior published trials by other companies, and capitalize on the properties of our product candidate. We have designed our Leadership trial to:

- require cystoscopic confirmation of inflammation of a patient s bladder for entry in the trial to ensure the enrollment of the proper patient population;

- measure patients over a six-week period, which we believe will provide a measure of therapeutic activity of AQX-1125 over a period that should both be sufficient to see improvement in pain and urinary symptoms but also long enough to minimize the risk that placebo effects could confound the trial results;

utilize a trial size sufficient to detect a change in pain, which is our primary endpoint, as measured by electronic diaries; and

administer a once daily oral 200 mg capsule dose that we expect to achieve concentrations both in the blood stream and in the urine that are significantly higher than we anticipate is required to activate SHIP1 in affected tissues.

Atopic Dermatitis

AD, often referred to as atopic eczema or just eczema, is an uncomfortable, relapsing, non-contagious, inflammatory skin disorder that is typically characterized by dry, itchy skin. AD lesions have a tendency to weep, crack, swell or crust-over and are at heightened risk for infection. AD symptoms manifest as redness, scaling, and loss of the surface of the skin. Atopic dermatitis is the most common of the many types of eczema and is frequently associated with other allergic disorders, especially asthma and hay fever. AD has been traced to a defect of the immune system within the skin but the cause of the disease is largely unknown, although a genetic component is well-recognized. The prevalence of AD in adults and children ranges from 1%-20% worldwide. An estimated 17.8 million people in the United States are affected by AD, which is considered under diagnosed by physicians. Approximately two-thirds of people in the United States diagnosed with AD suffer from the moderate to severe form of the disease, where existing therapies are often ineffective or unsuitable for long-term treatment.

AD is diagnosed based on the presentation of pruritis (itchy skin) in association with two to three other typical AD symptoms, which could include dry, scaly skin, the presence of papules, skin lesions, oozing rash, inflammation, and lichenification (thickening of the skin). Rashes and papules generally appear on the hands, ankles, neck or behind the knees or elbows. Bleeding and/or secondary infections are more common in severe cases of AD. Flares of AD are diagnosed as mild, moderate, or severe, although symptoms can occur at all levels of severity at varying degrees of intensity. Patients may be diagnosed with severe or refractory AD based on the symptoms appearing over a large area of the body, the intensity of the symptoms and the impact on the patient s quality of life. Failure to respond to treatment may also lead to a diagnosis of severe AD.

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AD Current Therapies There is no known cure for AD. Most current therapies and those in development are intended to alleviate symptoms, improve the condition of the skin, reduce the number of flares, and improve the patient s quality of life. Treatment is complex due to varying efficacy among products and individual response to therapies over time. Treatment generally consists of a combination of preventative care, such as keeping the skin hydrated and avoiding allergens, and therapies to reduce and alleviate symptoms as well as lengthen the remission period between flares. Mild AD is generally treated through patient education in conjunction with the use of emollients and bath oils while moderate disease often adds topical corticosteroids into the treatment paradigm.

While there is no standardized treatment algorithm, severe or refractory patients are typically prescribed higher potency topical corticosteroids with the potential addition of topical calcineurin inhibitors (TCIs) and/or systemic corticosteroids. Though higher potency topical corticosteroids are generally considered efficacious, efficacy can vary depending on the individual patient s severity of disease, use of the product, and the product itself. Furthermore, higher potency topical corticosteroids are not recommended for sensitive areas such as the face, are not suitable for prolonged use, and are not effective in treating pruritis.

TCIs are normally prescribed when a patient is not, or is no longer, responding adequately to treatment with topical corticosteroids, to treat sensitive areas of the body in concert with topical corticosteroids, or if a patient has concerns about the side effects of corticosteroid treatment. However, TCIs are only indicated for short-term non-continuous use as side effects can include burning, itching, and/or sensitivity to light.

Systemic corticosteroids are also sometimes administered in the short-term to control severe flares that are not responding to other therapies. Because of their safety profile, they are not generally used for on-going or chronic treatment. These systemic corticosteroids can be injected, inhaled, or taken orally.

Daily applications of, or applications multiple times per day with, topical therapies can be inconvenient or impractical for severe patients whose percent body surface area (%BSA) affected with AD is often higher than 25%, thus oral therapies can offer significant potential advantages for AD patients. Despite precedents for anti-inflammatory AD therapies, there are no oral anti-inflammatory therapies currently approved by the FDA for AD. We believe there is a significant medical need for new and innovative treatments that target the underlying inflammatory disease process and that reduce the severity, duration and reoccurrence of flares while having a safety profile potentially more suitable for prolonged use.

The Kinship Trial: AQX-1125 in AD patients *Our Phase 2 trial, known as the Kinship trial, is* investigating the ability of AQX-1125, compared to placebo, to improve AD symptoms. This trial is a randomized, double-blind, multicenter, placebo-controlled Phase 2 trial evaluating the efficacy and safety of AQX-1125 once daily oral 200 mg capsules for twelve weeks in approximately 50 adult patients with mild to moderate atopic dermatitis in order to obtain proof of concept from patients suffering from this disease. The trial, which initiated enrolment in December 2014, is being conducted at clinical research centers in Canada and is anticipated to complete with full enrollment and initial results in the first quarter of 2016. Full results are expected to be submitted for publication and presented at a leading medical conference in 2016. The Kinship trial s primary endpoint is change from baseline in Total Lesion Symptom Score (TLSS) at Week 12 of treatment. The TLSS is a comprehensive assessment of AD symptoms where AQX-1125 may have a beneficial effect. Secondary endpoints include safety, pharmacokinetics and additional parameters for assessing AD symptoms.

Expanded Clinical Indications for AQX-1125

We have demonstrated compelling preclinical efficacy with AQX-1125 in a broad range of relevant inflammatory and fibrotic models of inflammation including models of respiratory, urinary and gastrointestinal tract and skin

inflammation. We have previously stated an intention to initiate a fourth Phase 2 trial in chronic rhinosinusitis with nasal polyps in the first half of 2015. To focus our resources, we intend to delay the initiation of this trial until after the completion of the Leadership and Flagship trials. We believe our preclinical data and clinical proof-of-concept trial results support the potential for AQX-1125 to treat a range of diseases characterized by mucosal inflammation such as, chronic sinusitis, nephritis, eosinophilic esophagitis and inflammatory bowel disease.

We are currently evaluating a range of clinical indications for inclusion into our development plan for AQX-1125. In addition to the relevance of SHIP1 as a target, and the properties of AQX-1125, each disease and patient population must also be considered based on its relative unmet medical need, market opportunity, the competitive environment and feasibility of clinical/regulatory pathway. We believe that there are multiple value creating opportunities in further expanding the clinical indications for which AQX-1125 is being evaluated.

Next Generation SHIP1 Activators

We have several next generation product candidates in preclinical development that are also SHIP1 activators and intend to advance these through additional preclinical evaluation.

We believe there are anti-inflammatory diseases that would be better addressed by next generation SHIP1 activators that have different properties from AQX-1125 such as concentrating in different tissues, having a different duration of action or being more suitable for different routes of administration.

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We also intend to explore the role of SHIP1 activators in the treatment of cancer. Academic scientists have shown that in certain immune cell cancers the suppressed activity of SHIP1 could play a central role in the deregulation of PI3K pathway and tumor growth. Restoration of the SHIP1 activity by activators may make immune cell cancers more susceptible to chemotherapy. In addition, there is evidence that activating SHIP1 can reduce the chronic inflammation surrounding solid tumors, making these tumors more susceptible to chemotherapy. The treatment of cancer by modulating the PI3K pathway via SHIP1 offers a potentially promising new approach to improve the treatment of either immune cell cancers or solid tumors.

We believe next generation product candidates in the treatment of inflammation and cancer offer significant market potential.

Strategy

We intend to maintain and strengthen our leadership position in the development of small molecule drugs that target SHIP1. We intend to participate in the potential commercialization of AQX-1125 and other potential drug candidates that we develop with a focus on building a targeted commercial infrastructure focusing on specialist physicians for the United States and Canada. For territories outside of the United States and Canada and to target primary care physicians globally, for which our potential drug candidates may have a market, it is our intention to identify a strategic partner to fully optimize the commercial potential of AQX-1125 and other potential drug candidates that we may develop. We have a management team with broad-based experience and expertise that span drug discovery through Phase 3 trials and regulatory filings. The key components of our strategy are to:

Target large, underserved markets with limited competition and an attractive path to approval. We prioritize clinical indications that are characterized by significant economic burden and are currently under-invested by the pharmaceutical industry, thereby limiting potential competition. We believe our current product candidate offers an innovative treatment option with an attractive approval pathway in COPD, BPS/IC and AD. COPD, for example, is estimated to affect up to 600 million people worldwide, with current inhaled therapies having modest effects on slowing progression or reducing exacerbations. Our Flagship trial targets unstable COPD patients in greatest need and with the highest likelihood of responding to anti-inflammatory therapy. We believe enrolling those who experience frequent exacerbations creates the opportunity to demonstrate effect with fewer patients and shorter required dosing.

Focus on successfully developing AQX-1125 for a range of inflammatory diseases. We are focused on successfully executing the completion of our current Phase 2 trials in COPD, BPS/IC and AD. We will undertake additional work necessary for regulatory approval that may reduce the overall development time. Some of these activities are already underway and others will be undertaken in the future. These activities include: chronic toxicity studies in rat and dog and reproductive toxicity studies; chemistry, manufacturing and control, or CMC activities, including final dosage form development, process development, additional active pharmaceutical ingredient, or API, and final drug product manufacturing, and process validation; and supportive clinical trial work. We also intend to initiate additional Phase 2 trials with AQX-1125 focusing on additional diseases of the respiratory, urinary and gastrointestinal tracts and skin that would complement our ongoing evaluation of AQX-1125 in COPD, BPS/IC and AD.

Advance our next generation compounds in indications not covered by AQX-1125. We believe there are anti-inflammatory diseases that would be better addressed by our next generation SHIP1 activators that have different properties from AQX-1125 such as concentrating in different tissues, having a different duration of action or being more suitable for different routes of administration. We already have a significant library of candidate compounds and will advance these through additional preclinical evaluation. We also intend to explore the role of SHIP1 activators in the treatment of cancer. Each of these applications offers significant market potential. We intend to advance one next generation product candidate for either an inflammatory disease or for the treatment of cancer to clinical trials by 2016.

Evaluate on a selective basis strategic partnerships to maximize the commercial potential of AQX-1125 and actively pursue partnerships for our next generation and other non-core assets. From a commercialization strategy perspective, we have intentionally maintained full commercial rights to our product candidates to date. A decision on partnering will be made at the time when our available data supports a well-defined path to approval and market, as this timing will enable us to capture maximum value from our product candidates. We intend to explore a variety of alternatives for the potential commercialization of AQX-1125 on a global basis, including direct commercialization, co-promotion or selective territorial out-licensing of rights to a third party. It is our intention to participate in the potential commercialization of AQX-1125 in the United States and Canada and to seek a strategic partner for other territories. By retaining worldwide rights to AQX-1125 through early development we have maintained flexibility for any future commercialization of AQX-1125. We intend to pursue a similar strategy for our next generation product candidates, except for those that require expertise outside our core-areas or require resources beyond those available to us. For non-core assets, as we advance our next generation product candidates, we intend to seek early partnerships to defray the cost, risk and infrastructure requirements in order to further their commercial development.

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Research and Development

Since commencing operations, we have dedicated a significant portion of our resources to the development of product candidates, particularly AQX-1125. We incurred research and development expenses of $18.1 million, $7.6 million and $6.0 million during the years ended December 31, 2014, 2013 and 2012, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to advance AQX-1125 and our future product candidates.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for AQX-1125 and our future product candidates, novel biological discoveries, screening and drug development technologies such as our SHIP1 discovery platform, manufacturing and process discoveries, and other inventions that are important to our business, as well as to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We strive to protect our intellectual property through a combination of patent, copyright, trademark and trade secrets laws, as well as through confidentiality provisions in our contracts.

With respect to AQX-1125 and our future product candidates, we endeavor to obtain and maintain patent protection in the United States and internationally on all patentable aspects of AQX-1125 and our other pipeline products, as it is critical to our global business strategy. Our patenting strategy is initially to pursue patent protection covering both compositions of matter and methods of use of AQX-1125 and our future product candidates and then seek to obtain additional patent protection throughout the development process on other aspects of our technology that would potentially enhance our competitive exclusivity and commercial success. Such additional means of protection may include filing applications with claims to additional methods of use, processes of manufacture, methods of screening, biomarkers, and companion diagnostics. We also rely on continuing technological innovation, know-how and trade secrets relating to our discovery platform and product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted, or the patent held invalid after issuance. Consequently, we may not be able to obtain or maintain adequate patent protection for AQX-1125 or any of our future product candidates. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see the section of this Annual Report captioned Risk Factors Risks Related to Intellectual Property.

Our patent estate on a worldwide basis includes approximately 27 issued patents and approximately 17 pending patent applications that we are actively prosecuting and/or maintaining. These figures include patents and patent applications to which we hold exclusive commercial rights under our licenses from third parties. Our solely owned issued patents include seven U.S. patents and 11 foreign patents and our solely owned patent applications include one U.S. application and 12 foreign patent applications.

Intellectual Property Relating to AQX-1125

We are the sole owner of a patent portfolio that includes issued patents and pending patent applications covering compositions of matter and methods of use of AQX-1125. We acquired these patents and applications relating to AQX-1125 by way of an asset purchase from Biolipox AB in August 2009. This patent portfolio includes four issued United States patents and 11 foreign patents issued in Europe, Japan, Canada, Korea, Mexico, Norway, Russia, Australia and New Zealand. Our issued patents cover the composition of matter of both the class of compounds to which AQX-1125 belongs, and AQX-1125 specifically, as well as methods for using AQX-1125. The foreign patents will expire in 2024, while the U.S. patents will expire in 2024-28, excluding patent term extensions that may be available in the United States under the Hatch-Waxman Act or in foreign countries under similar statutes. The expiration dates of the issued U.S. patents relating to AQX-1125 include patent term adjustment (PTA) under the provisions of 35 U.S.C. §154; namely, we have received a PTA extension of 1,379 days for U.S. Patent 7,601,874, which covers the composition of matter of AQX-1125, and a PTA extension of 58 days for U.S. Patent 8,084,503 which covers the methods of using AQX-1125.

Patent Terms

The term of individual patents and patent applications listed in previous sections will depend upon the legal term of the patents in the countries in which they are obtained. In most countries, the patent term is 20 years from the date of filing of the patent application (or parent application, if applicable). For example, if an international Patent Cooperation Treaty, or PCT, application is filed, any patent issuing from the PCT application in a specific country expires 20 years from the filing date of the PCT application. In the United States, however, if a patent was in force on June 8, 1995, or issued on an application that was filed before June 8, 1995, that patent will have a term that is the greater of 20 years from the filing date or 17 years from the date of issue.

In the United States, the Hatch-Waxman Act permits the patent term of a patent that covers an FDA-approved drug to be eligible for patent term extension, or PTE, of up to five years beyond the original expiration of the patent. This patent term restoration acts as compensation for the patent term lost during product development and the FDA regulatory review process if approval of the

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application for the product is the first permitted commercial marketing of a drug or biological product containing the active ingredient. The length of the patent term extension is related to the length of time the drug is under regulatory review, and is generally one-half the time between the effective date of an IND and the submission date of a NDA plus the time between the submission date of a NDA and the approval of that application. Patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we anticipate applying for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Trade Secrets

In addition to patents, we also rely upon proprietary know-how (including trade secrets) to protect our technology and maintain and develop our competitive position. In some situations, maintaining information as a trade secret may be more appropriate to protect the type of technology than filing a patent application. We seek to protect our confidential and proprietary information in part by confidentiality agreements and it is our policy to require employees, consultants, scientific advisors, outside scientific collaborators, sponsored researchers, and contractors to execute such agreements upon the commencement of a relationship with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. We also employ invention assignment clauses in our agreements to grant us ownership of technologies that are developed through a relationship with a third party. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee s use of our confidential information are our exclusive property. We also seek to preserve our trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information or otherwise gain access to, or disclose, our trade secrets. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see the section of this Annual Report captioned Risk Factors Risks Related to Intellectual Property.

Contractual Obligations Related to Intellectual Property

On August 19, 2009, AQXP Canada entered into an asset purchase agreement with Biolipox AB of Sweden, or Biolipox, for the purchase of all assets, including patent rights and know-how, relating exclusively or principally to a compound library from which we ultimately identified and selected AQX-1125. Under the terms of the agreement, AQXP Canada paid Biolipox Canadian $50,000 immediately upon closing. An additional Canadian $250,000 by way of issuance of 19,762 shares of our common stock was made in June 2014 upon the first submission to the FDA of an IND for a compound from the acquired class. The terms of the agreement also require a one-time Canadian $3 million milestone payment upon the commitment of financial resources by the Board of Directors of AQXP Canada to advance AQX-1125 into a Phase 3 clinical trial. We will also be required to make certain other milestone payments

totaling up to Canadian $1.5 million in the aggregate upon the first commercial sale of the first compound covered by the acquired patent rights (which we expect will be triggered by the first commercial sale of AQX-1125) in each of the United States, Europe and Japan.

AQXP Canada entered into an exclusive license agreement with the University of British Columbia, or UBC, in June 2006, for certain patent rights and technology relating to small molecule compounds and pharmaceutical compositions as modulators of SHIP1 activity. This agreement was amended and restated in June 2007, and subsequently amended in October 2006, June 2007, September 2008 and April 2010. This agreement will expire at the last to expire issued patent covering the licensed technology. The agreement will terminate automatically upon our insolvency or may be terminated by either party for material breach by the other party. The terms of the agreement required AQXP Canada to pay an initial license fee of Canadian $50,000, all of which was paid by the issuance of 5,208 common exchangeable shares of AQXP Canada. We do not currently have any product candidates under development that are covered by the agreement, nor have we sublicensed our rights under the licensed patents. However, if we develop products covered by the UBC technology in the future, we will be required to pay certain development and regulatory milestones up to an aggregate of Canadian $2.2 million for the first drug product developed under the license and up to Canadian $1.5 million for each subsequent drug product, which may be paid in cash or by issue of our shares. We must also pay UBC low single-digit royalties based on aggregate worldwide net sales of products covered by the licensed patents and a percentage of sublicensing revenue ranging from the low single digits to the mid double digits based on the stage of development at which such sublicense is granted. We are also required to reimburse costs incurred by UBC related to the prosecution and maintenance of the licensed patents, and to pay an annual license maintenance fee.

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In May 2005, AQXP Canada entered into an assignment agreement, which was subsequently amended in December 2005 and March 2006, with the British Columbia Cancer Agency (BCCA) and StemCell Technologies, Inc. (STI), for the assignment to AQXP Canada of the 2002 exclusive license agreement between BCCA and STI to certain patents relating to technology relating to SHIP1. The license agreement between AQXP Canada and BCCA was amended and restated on August 9, 2006 and on June 8, 2007. This agreement has subsequently been amended in June 2008 to revise the schedule of the technology licensed under this agreement, and further amended in February 2013. Pursuant to this agreement, as amended, BCCA has granted us an exclusive worldwide license to certain of its intellectual property relating to core SHIP1 technology, and screening of compounds for activity using SHIP1, including the C2 binding domain. The agreement is to expire at the later of 20 years from the effective date of the agreement or upon the expiration of the last patent covered by the license. The terms of the assignment agreement among STI, BCCA and AQXP Canada required AQXP Canada to pay an assignment license fee of Canadian $150,000, paid in stages beginning May 2005 and ending March 2006. We do not currently have any product candidates under development that are covered by the BCCA license agreement, nor have we sublicensed our rights under the licensed patents. However, if we develop products covered by the BCCA technology in the future, we will be required to pay BCCA low single-digit royalties based on aggregate worldwide net sales of products covered by the licensed patents, and if we sublicense any rights to the technology, a low double digit percentage of sublicensing revenue. We are also required to reimburse BCCA s patent costs incurred in relation to the licensed technology, and pay an annual maintenance fee in the amount of Canadian $5,000. Our license with BCCA will terminate automatically upon our insolvency, and may be terminated by either party for material breach by the other party.

General Considerations

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify a proprietary position for our product candidates will depend upon our success in obtaining effective patent claims and enforcing those claims once granted.

Our commercial success will depend in part upon not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. If a third party commences a patent infringement action against us, or our collaborators, it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation, intense competition and a strong emphasis on proprietary products. While we believe that our SHIP1 and related technologies, product candidates, intellectual property, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from other pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

COPD

Inhaled bronchodilators, such as long-acting beta-2 adrenergic agonists (LABAs) and long-acting muscarinic antagonists (LAMAs), alone or in combination with each other or with inhaled corticosteroids (ICSs), are central to the symptomatic treatment of COPD. Companies competing in this space with inhaled bronchodilators include GlaxoSmithKline (fluticasone/salmeterol LABA/ICS combination (Advair)), Boehringer Ingelheim/Pfizer (tiotropium LAMA (Spiriva)) and AstraZeneca (formoterol/budesonide LABA/ICS (Symbicort)). Recent inhaled bronchodilator approvals include GlaxoSmithKline/Theravance s once-daily LABA/ICS combination fluticasone/vilanterol (Breo Ellipta), Almirall SA s twice-daily LAMA aclidinium (Tudorza Pressair) and Novartis AG s once-daily LABA indacterol (Onbrez Breezhaler). Companies with inhaled products in Phase 3 clinical trials or pending approval in the United States include GlaxoSmithKline/Theravance (umeclidinium, vilanterol LAMA (Anoro)), Novartis (glycopyrrolate/indacaterol LABA/LAMA (Ultibro Breezhaler)) and Boehringer Ingelheim (olodaterol LABA).

Currently, the only oral anti-inflammatory approved by the FDA for the treatment of COPD is Takeda Pharmaceuticals International GmbH s Phosphodiesterase-4 (PDE4) inhibitor, roflumilast, marketed in the United States by Forest Laboratories, Inc. as DALIRESP. Roflumilast s success has been limited by its modest efficacy, safety and tolerability profile. To our knowledge, there are no Phase 3 trials being conducted for any new anti-inflammatory therapies. We are aware of several other companies developing novel oral anti-inflammatory therapies that are in various stages of clinical development for the treatment of COPD including Pfizer (PH-797804), Pfizer/Revotar (TBC-1269), AstraZeneca (AZD-5069), GlaxoSmithKline (GW-856553) and Novartis (BCT-197). However, we believe our novel anti-inflammatory therapy, AQX-1125, remains one of the most advanced in clinical development.

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BPS/IC

Few treatments exist for BPS/IC and bladder instillations remain the mainstay therapy for symptomatic relief of BPS/IC with intravesical administration of analgesics, DMSO, sodium hyaluronate, heparin and cocktails of the same being typical. There are no oral anti-inflammatories approved by the FDA for the treatment of BPS/IC; however, the leading oral therapy approved by the FDA is Janssen Pharmaceuticals Inc. s pentosan polysulfate sodium, marketed in the United States as Elmiron. We are aware of several other companies developing competing therapies that are in various stages of development for the treatment of BPS/IC. Companies competing in this space include AbbVie (Humira), Pfizer (tanezumab), Urigen (URG101), TARIS (LiRIS) and Afferent (AF219).

AD

Though many treatments exist for mild to moderate AD given a proliferation of emollients and other products that improve the condition of the skin, few therapies or treatment options exist for severe disease and higher potency topical corticosteroids remain the mainstay therapy for severe AD patients with administration of TCIs or systemic corticosteroids being typical for short-term control of flares and/or refractory patients. There are no oral anti-inflammatories approved by the FDA for the treatment of AD; however, the leading topical immunosuppressant therapies approved by the FDA are Meda AB s pimecrolimus, marketed in the United States as Elidel, and Astellas Pharma Inc s tacrolimus, marketed in the United States as Protopic. We are aware of several other companies developing competing therapies that are in various stages of development for the treatment of severe AD, in particular biologics. Companies competing in this space include Novartis (omalizumab anti-IgE (Xolair)), Biogen Idec (rituximab anti-CD20 (Rituxan)), Janssen s (infliximab anti-TNF (Remicade)), and Regeneron (dupilumab anti-IL-13R/IL-4R).

We believe that AQX-1125 may offer potential advantages over competitive products that could enable it, if approved, to capture meaningful market share from our competitors. However, many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also compete with us, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Manufacturing

We conduct our manufacturing activities for our clinical development of our product candidates under individual purchase orders with third-party contract manufacturing organizations (CMOs) as we currently have no manufacturing facilities and do not intend to develop one. We have in place quality agreements with our key CMOs. We have also established an internal quality management system, which audits and qualifies CMOs. Our third-party manufacturers, their facilities and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with current Good Manufacturing Practices (cGMP).

AQX-1125 is a small molecule capable of being manufactured in reliable, reproducible, and scalable synthetic processes from readily available starting materials. We believe the chemistry used to manufacture AQX-1125 is

amenable to scale up and does not require unusual equipment in the manufacturing process. One of our CMOs is currently manufacturing active pharmaceutical ingredient (API) on multi-kilogram scale, for use in preclinical and clinical development of AQX-1125. A second CMO produces AQX-1125 final drug product for use in our ongoing clinical trials. We believe that the manufacturing processes for AQX-1125 API and final drug product have been developed to adequately support current development. For future development and commercial demands, additional CMO activities will be required for API process development, API manufacturing validation, and final drug product formulation. We believe that our existing suppliers of AQX-1125 API and drug products would be capable of providing sufficient quantities of the AQX-1125 API and drug products to meet anticipated commercial demands.

The FDA and other health authorities worldwide regulate and inspect equipment, facilities and processes used in manufacturing pharmaceutical products prior to approval. If we fail to comply with applicable cGMP requirements and conditions of product approval, the FDA may seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party CMOs, we cannot be certain that our present or future third-party CMOs will consistently comply with cGMP and other applicable FDA regulatory requirements.

Commercial Operations

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States and Canada, such commercial infrastructure could be expected to include a targeted, sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that AQX-1125 will be approved.

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Government Regulation

As a pharmaceutical company that operates and anticipates seeking approval for pharmaceutical product candidates in the United States, we are subject to extensive regulation by the FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Our pharmaceutical product candidates must be approved by the FDA before we can commence clinical trials or market those products in the United States.

Although the discussion below focuses on regulation in the United States, we conduct research activities and anticipate seeking approval for, and marketing of, our products in other countries and regions, such as Canada and Europe. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

FDA Regulation

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDC Act. Pharmaceutical products are also subject to other federal, state and local statutes. A failure to comply with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an institutional review board, or IRB, of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The steps required before a new drug may be marketed in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with current good clinical practices, or GCPs, to establish the safety and efficacy of the investigational drug product for each targeted indication;

submission of New Drug Application, or NDA, to the FDA;

satisfactory completion of an FDA Advisory Committee review, if applicable;

satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate; and

FDA review and approval of the NDA.

Clinical Trials

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. This authorization is required before interstate shipping and administration of any new drug product to humans that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required. The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are generally described as follows:

Phase 1 Phase 1 includes the initial introduction of an investigational drug into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition or healthy volunteers. These trials are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product s pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

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Phase 2 Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase 3 Phase 3 clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The decision to terminate development of an investigational drug product may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of drugs on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of a NDA to request market approval for the product in specified indications.

New Drug Applications

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the drug product for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product s chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to 12 months of filing. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA does not always achieve its performance goal and its review of NDAs can take significantly longer. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in

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accordance with cGMP. The FDA may refer applications for novel drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The approval process is lengthy and difficult and notwithstanding the submission of any requested additional information, the FDA ultimately may refuse to approve an NDA if applicable regulatory criteria are not satisfied or if the FDA believes additional clinical data or other data and information are required. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than a company interprets the same data.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. FDA s approval of a product may be significantly limited to specific disease and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for off-label uses that is, uses not approved by the FDA and therefore not

described in the drug s labeling because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice (DOJ), or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Post-Approval Regulations

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. In addition, as a holder of an approved NDA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long term stability of the drug or biological product. The cGMP requirements apply all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

Newly discovered or developed safety or effectiveness data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA s imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Comparable European, Canadian and Other International Government Regulation

In addition to FDA regulations in the United States, we will be subject to a variety of comparable regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

Some countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed. To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application, or MAA. The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements.

In Canada, biopharmaceutical product candidates are regulated by the Food and Drugs Act and the rules and regulations promulgated thereunder, which are enforced by the Therapeutic Products Directorate of Health Canada, or

TPD. Before commencing clinical trials in Canada, an applicant must complete preclinical studies and file a CTA with the TPD. After filing a CTA, the applicant must receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. To obtain regulatory approval to commercialize a new drug in Canada, a new drug submission, or NDS, must be filed with the TPD. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities rules, regulations and guidelines and demonstrates favorable safety and efficacy and receives a favorable risk/benefit analysis, the TPD issues a notice of compliance which allows the applicant to market the product.

For other countries outside of the European Union and Canada, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to additional regulation and oversight under other healthcare laws by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. These laws include the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common

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activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor from federal Anti-Kickback Statute liability. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, further strengthened these laws by amending the intent standard under the Anti-Kickback Statute and the criminal health care fraud statutes (discussed below) to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below).

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies marketing of the product for off-label, and thus, non-covered, uses.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members and payments or other transfers of value to such physician owners and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/ or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. In addition, our future commercial activities may also be subject to federal and state consumer protection and unfair competition laws.

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If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicaid and Medicare, injunctions, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent that third-party payors provide coverage, and establish adequate reimbursement levels for such drug products. In the United States, third-party payors include federal healthcare programs, state healthcare programs, managed care providers, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. AQX-1125 or our future product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If a drug product is reimbursed under a governmental healthcare program, such as Medicare, Medicaid or TRICARE, additional laws and program requirements will apply.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for drugs, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. The European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In March 2010, President Obama signed the Affordable Care Act, which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical industry. The Affordable Care Act impacts existing government healthcare programs and requires the development of new programs. For example, the Affordable Care Act provides for Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Among the Affordable Care Act s provisions of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs, that began in 2011;

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an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of AMP;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers outpatient drugs to be covered under Medicare Part D;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

new requirements to report annually specified financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other transfers of value to such physician owners and their immediate family members; a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners, pharmacies of hospitals and other healthcare entities; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Affordable Care Act also establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. Beginning in 2014, IPAB is mandated to propose changes in Medicare payments if it determines that the rate of growth of Medicare expenditures exceeds target growth rates. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for pharmaceutical products. A proposal made by the IPAB is required to be implemented by CMS unless Congress

adopts a proposal with savings greater than those proposed by the IPAB. IPAB proposals may impact payments for physician and free-standing services beginning in 2015 and for hospital services beginning in 2020.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

We anticipate that the Affordable Care Act will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

Anti-Corruption Legislation

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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The Corruption of Foreign Public Officials Act, or CFPOA, prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Under the CFPOA, companies may be liable for the actions of their employees or third-party agents, even if such persons operate outside of Canada.

Employees

As of December 31, 2014, we had 24 employees, of whom five hold Ph.D. degrees or M.D. degrees. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We believe that relations with our employees are good.

Corporate Information

We commenced operations as 6175813 Canada Inc., a corporation formed in December 2003 under the Canada Business Corporations Act. In May 2014, after a corporate restructuring, we changed the name of such entity to Aquinox Pharmaceuticals (Canada) Inc. We incorporated Aquinox Pharmaceuticals (USA) Inc., a corporation under the laws of the State of Delaware, in May 2007. We subsequently changed the name of this corporation in January 2014 to Aquinox Pharmaceuticals, Inc. AQXP Canada is a wholly owned subsidiary of Aquinox USA. Our primary executive offices are located at 450-887 Great Northern Way, Vancouver, B.C., Canada V5T 4T5 and our telephone number is (604) 629-9223. Our website address is www.aqxpharma.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report.

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Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this annual report on Form 10-K and the information incorporated by reference herein. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed.

This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future.

We are a clinical-stage pharmaceutical company with a limited operating history. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing or commercial sale and have not generated any revenue from product sales, or otherwise, to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2003. For the years ended December 31, 2014, 2013 and 2012, we reported a net loss of $24.0 million, $8.7 million and $7.7 million, respectively. As of December 31, 2014, we had an accumulated deficit since inception of $89.4 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue the research and development of, and seek regulatory approvals for, AQX-1125 and any of our future product candidates, and potentially begin to commercialize any products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our financial condition. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our financial condition. If AQX-1125 or any future product candidate fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been primarily limited to organizing and staffing our company, acquiring product and technology rights, discovering and developing novel small molecule drug candidates and undertaking preclinical studies and clinical trials of AQX-1125. We have not yet obtained regulatory approval for AQX-1125 or any future product candidate. Consequently, evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future

collaborators, to successfully commercialize products, including AQX-1125 or any future product candidates that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for AQX-1125 or any future product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from product sales from AQX-1125 or any of our future product candidates also depends on a number of additional factors, including our or any future collaborators ability to:

- complete development activities, including the necessary clinical trials;
- complete and submit new drug applications, or NDAs, to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;

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obtain coverage and adequate reimbursement from third-party payors, including government and private payors;

achieve market acceptance for our products, if any;

establish, maintain and protect our intellectual property rights; and

attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that AQX-1125, or any future product candidates, may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we are able to complete the development and regulatory process for AQX-1125 or any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of AQX-1125 or any future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Our operating results may fluctuate significantly on a quarterly and annual basis, which may make our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results have varied significantly in the past and may continue to fluctuate significantly in the future from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control, which may make it difficult for us to predict our future operating results. Factors that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this report:

our ability to obtain additional funding for research and development and manufacturing activities relating to AQX-1125 or any of our future product candidates;

the timing and cost of research and development activities relating to AQX-1125 or any of our future product candidates, which may change from time to time;

the cost of manufacturing AQX-1125 or any of our future product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;

expenditures that we will or may incur to acquire or develop additional product candidates and technologies;

the level of demand for AQX-1125 or any of our future product candidates, should they receive approval, which may vary significantly;

our ability to enroll patients in clinical trials;

the success or failure of clinical trials through all phases of clinical development for AQX-1125 or any of our future product candidates or competing product candidates, including our Phase 2 trials of AQX-1125, or any other change in the competitive landscape of our industry;

any delays in regulatory review and approval of AQX-1125 or any of our future product candidates;

potential side effects of AQX-1125 or our future product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;

the ability of patients or healthcare providers to obtain coverage of, or sufficient reimbursement for, AQX-1125 or our future product candidates and our ability to achieve acceptance among patients and physicians;

competition from existing and potential future drugs that compete with AQX-1125 or our future product candidates;

our ability to receive approval and commercialize AQX-1125 or our future product candidates outside of the United States;

our dependency on third-party manufacturers to supply or manufacture our AQX-1125 or our future product candidates;

our ability to establish or maintain collaborations, licensing or other arrangements;

our ability and third parties abilities to protect intellectual property rights;

costs related to, and outcomes of, potential intellectual property litigation;

costs associated with recently enacted healthcare legislation;

our ability to adequately support future growth;

our ability to attract and retain key personnel to manage our business effectively;

our ability to build our finance infrastructure and improve our accounting systems and controls;

potential product liability claims;

potential liabilities associated with hazardous materials;

fluctuations in foreign currency exchange rates;

our ability to use potential future operating losses and our federal and state net operating loss carryforwards to offset taxable income;

potential unforeseen business disruptions that increase our costs or expenses;

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our ability to maintain adequate insurance policies; and

the changing and volatile U.S., European and global economic environments.

Investors should not rely on our quarterly or annual results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We are likely to require additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of AQX-1125 or develop future product candidates.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. Our operations have consumed substantial amounts of cash since inception. We expect research and clinical development expenses to increase substantially in connection with our ongoing activities, particularly as we advance AQX-1125 or future product candidates in clinical trials and launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial organization. We believe that our existing cash and cash equivalents and interest thereon will be sufficient to fund our operating requirements for at least the next 12 months. However, circumstances may cause us to consume capital more rapidly than we anticipate. We will likely require additional capital for the further development and potential commercialization of AQX-1125 or future product candidates and may also need to raise additional funds sooner to pursue a more accelerated development of AQX-1125 or future product candidates.

If we need to secure additional financing, additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize AQX-1125 or future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

significantly delay, scale back or discontinue clinical trials related to the development or commercialization of AQX-1125 or any of our future product candidates or cease operations altogether;

seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or

relinquish, or license on unfavorable terms, our rights to AQX-1125 or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for AQX-1125 and any future product candidates;
- the clinical development plans we establish for AQX-1125 or any future product candidates;
- the achievement of milestones and our obligation to make milestone payments under our present or any future in-licensing agreements;
- the number and characteristics of product candidates that we discover or in-license and develop;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- the effect of competing technological and market developments;
- the costs and timing of the implementation of commercial-scale outsourced manufacturing activities; and
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in territories where we choose to commercialize products on our own.

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If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our business, results of operations, financial condition and cash flows and future prospects could be materially adversely affected.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, AQX-1125 or any future product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to finance future cash needs through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Additional capital may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities that could result in dilution to our existing stockholders, and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that include restrictive covenants limiting our ability to take important actions and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, AQX-1125 or our future product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use NOL carryforwards could be limited as a result of issuance of equity securities.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations or corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we issue. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow and future prospects.

The acquisition of control of AQXP Canada could result in adverse Canadian tax consequences, including limitations on AQXP Canada s ability to use non-capital loss carryforwards and other similar tax attributes to offset taxable income for Canadian tax purposes.

We underwent a reorganization immediately prior to the closing of our initial public offering (IPO) in March 2014 which resulted in AQXP Canada becoming a wholly owned subsidiary of Aquinox USA through an exchange of shares. Under the Income Tax Act (Canada), referred to herein as the Tax Act, in connection with the exchange of shares of AQXP Canada for shares of Aquinox USA, there may be limitations on AQXP Canada s ability to use its non-capital loss carryforwards and other similar tax attributes following the acquisition of control. In general, an

acquisition of control would result in AQXP Canada losing its net capital loss carryforwards, if any, and AQXP Canada s non-capital loss carryforwards and other similar tax attributes only being useable to offset income, excluding capital gains, derived from the business operated by AQXP Canada that generated such tax attributes or a business similar to such business and provided the business that generated the tax attributes continues to be carried on by AQXP Canada for profit or with a reasonable expectation of profit. We expect that we will continue to carry on the business of AQXP Canada for profit or with a reasonable expectation of profit and that, accordingly, its non-capital loss carryforwards and other similar tax attributes should be available to offset future income for Canadian tax purposes to the extent of income from that business or similar businesses, subject to expiry of such loss carryforwards over time pursuant to the provisions of the Tax Act. If our use of these non-capital loss carryforwards or other similar tax attributes is restricted as a result of an acquisition of control or otherwise, our Canadian federal income tax liability may be materially increased, which could adversely affect our business, results of operations, financial condition and cash flow and future prospects.

Fluctuations in foreign currency exchange rates could result in changes in our reported revenues and earnings.

We currently incur significant expenses denominated in foreign currencies, specifically in connection with our operations in Canada. In addition, we utilize numerous clinical trial sites as part of our clinical trials for AQX-1125, most of which are located in various countries outside of the United States. These clinical trial sites invoice us in the local currency of the site. We do not engage in foreign currency hedging arrangements for our accounts payable, and, consequently, foreign currency fluctuations may adversely affect our earnings. We may decide to manage this risk by hedging our foreign currency exposure, principally through derivative contracts. Even

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if we decide to enter into such hedging transactions, we cannot be sure that such hedges will be effective or that the costs of such hedges will not exceed their benefits. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the Canadian dollar, could result in material amounts of cash being required to settle the hedge transactions or could adversely affect our financial results.

Risks Related to Our Business and Industry

Our future success is dependent primarily on the regulatory approval and commercialization of AQX-1125 and any of our future product candidates.

We do not have any products that have gained regulatory approval. Currently, our only clinical-stage product candidate is AQX-1125, which is undergoing Phase 2 clinical trials.

As a result, our near-term prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize AQX-1125 in a timely manner. We cannot commercialize AQX-1125 or our future product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize AQX-1125 or our future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes more than a year to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of AQX-1125 or our future product candidates for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials, generally including two well-controlled Phase 3 trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Obtaining regulatory approval for marketing of AQX-1125 or our future product candidates in one country does not ensure we will be able to obtain regulatory approval in other countries but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if AQX-1125 or any of our future product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for AQX-1125 in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any of our future product candidate that we may discover, in-license, develop or acquire in the future. Also, any regulatory approval of any of AQX-1125 or our future product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for AQX-1125, the commercial success of AQX-1125 will depend on a number of factors, including the following:

- development of a commercial organization or establishment of a commercial collaboration with a commercial infrastructure,

- establishment of commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors;

the ability of our third-party manufacturers to manufacture quantities of AQX-1125 using commercially sufficient processes and at a scale sufficient to meet anticipated demand and enable us to reduce our cost of manufacturing;

our success in educating physicians and patients about the benefits, administration and use of AQX-1125;

the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

the effectiveness of our own or our potential strategic collaborators marketing, sales and distribution strategy and operations;

acceptance of AQX-1125 as safe and effective by patients and the medical community; and

a continued acceptable safety profile of AQX-1125 following approval.

Many of these factors are beyond our control. If we, or our potential commercialization collaborators, are unable to successfully commercialize AQX-1125, we may not be able to earn sufficient revenues to continue our business.

Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results, AQX-1125, which is currently in Phase 2 clinical trials, or any future product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for AQX-1125, we do not know whether the clinical trials we are conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market AQX-1125 or any of our future product candidates in any particular jurisdiction. Even if we believe that we have adequate data to support an application for regulatory approval to market our product candidates, FDA or other applicable foreign regulatory authorities may not agree and may require we conduct additional clinical trials. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

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In the Phase 2 trial we are conducting to evaluate the effect of AQX-1125 on COPD patients, we are enrolling only unstable moderate to severe COPD patients at the time of or following a recent exacerbation. We believe this novel trial design will allow us to measure sufficient symptoms and clinical events to detect the effects of AQX-1125 on the change in the severity, duration and reoccurrence of exacerbations in COPD patients as measured by a change in EXACT scores as the primary endpoint in a 12 week trial. The EXACT-PRO is a validated 14-item questionnaire to be completed daily by the patient on an electronic diary to assess the change in symptoms associated with a COPD exacerbation. Answers are converted into a numerical score between 0-100. By comparing the daily scores over a 12 week period for patients receiving AQX-1125 versus those receiving placebo we believe we can measure the effects of AQX-1125 on the change in the severity, duration and reoccurrence of exacerbations in COPD patients more sensitively than with traditional endpoints such as lung function measures or numbers of medically reported exacerbations. The FDA has accepted our IND application for the Flagship trial and we shared the use of EXACT-PRO as our primary endpoint for this trial; however, we do not know whether the FDA will accept EXACT-PRO as a primary endpoint for Phase 3 trials. In January 2014, the FDA issued draft guidance on the use of EXACT-PRO for clinical trials. The FDA stated that the EXACT-PRO is qualified as a well-defined and reliable measure of symptoms of exacerbations of COPD, for use in Phase 2 trials. Additional development work is needed to further assess measurement properties over the course of an exacerbation, including ability to detect meaningful change in response to an acute intervention. We are not aware of any other clinical trial utilizing EXACT scores as a primary endpoint in a Phase 2 or Phase 3 trial over 12 weeks. If the FDA does not accept EXACT-PRO as a primary endpoint in Phase 3 trials, it could delay our ability to advance AQX-1125 into clinical trials for marketing approval in COPD, and the FDA may require that we use other clinical COPD measures, such as Forced Expiratory Volume in one second (FEV_1), a measure of lung function that is reduced in COPD, as the primary endpoint, rather than EXACT-PRO. Even if the FDA accepts EXACT-PRO for our Phase 3 trials and our Phase 2 clinical trial in COPD supports advancement of Phase 3 clinical trials, the trial duration may need to be longer than the 12 weeks of our current Phase 2 trial.

In addition, we have not yet established the optimal dose for AQX-1125. There can be no guarantee that the 200 mg dose currently being studied in our Phase 2 clinical trial will be efficacious or, if it is, whether it will be the optimal dose. We believe we will need to conduct additional clinical trials to evaluate additional dose levels of AQX-1125. There cannot be any guarantee that any of these trials will be successful in determining a dose of AQX-1125 suitable for marketing approval.

SHIP1 has not been validated as a target.

Our primary focus is small molecule anti-inflammatory product candidates targeting SHIP1, which is a key regulator of an important cellular signaling pathway in immune cells. To date, no drug which specifically targets SHIP1 has been demonstrated to provide clinical benefit or been approved by any regulatory authority for the treatment of disease. Therefore, SHIP1 has not been validated as a target. We are therefore pursuing development of AQX-1125 against a novel and unproven target. We believe AQX-1125 is the only SHIP1 activator currently in clinical trials. SHIP1 activators as a class of drug, including AQX-1125, may ultimately prove unsuitable for treatment of human diseases, or if approved for treatment of human diseases, may be commercially unsuccessful, either of which could cause our business to fail.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and early clinical trials.

We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. While we do not anticipate any future delays, there can be no assurance that the FDA or other comparable foreign regulatory authority will not put clinical trials of AQX-1125 or any other of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;

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withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

delay or failure in subjects completing a trial or returning for post-treatment follow-up;

clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;

delay or failure in adding new clinical trial sites;

ambiguous or negative interim results or results that are inconsistent with earlier results;

feedback from the FDA, the IRB, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for the trial;

decision by the FDA, the IRB, a comparable foreign regulatory authority, or us, to impose a clinical hold following an inspection of our clinical trial operations or trial sites, or recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;

failure to demonstrate a benefit from using a drug;

delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties; or

changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

As an organization, we have never conducted a Phase 3 clinical trial or submitted an NDA to the FDA or comparable foreign regulatory authorities before, and may be unable to do so for AQX-1125 or any product candidate we are developing.

We are currently conducting Phase 2 clinical trials and we may need to conduct additional Phase 2 clinical trials before initiating our Phase 3 clinical trials. If our additional Phase 2 clinical trials are successful, we intend to conduct Phase 3 trials of AQX-1125, either alone or with a future collaborator. The conduct of Phase 3 clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not conducted a Phase 3 clinical trial before, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. We also have had limited interactions with the FDA and comparable foreign authorities and have not discussed our proposed regulatory approval strategy with the FDA. Consequently, even if our Phase 2 clinical trials are successful, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of AQX-1125 or any other product candidate we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of products that we develop. Failure to commence or complete, or delays in, our planned clinical trials, would prevent us from, or delay us in, commercializing AQX-1125 or any other product candidate we are developing.

If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, delays or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. For example, we experienced delays in obtaining regulatory approvals to commence enrolling patents in Poland in our Flagship trial. In addition, we believe a milder than expected winter and flu season in Europe from late 2013 to early 2014 impacted the number of exacerbating COPD patients eligible to be enrolled in the Flagship trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. For example, in our Phase 1b LPS challenge proof-of-concept trial of AQX-1125, a large number of data points were lost for one part of the trial through error, rendering an analysis for efficacy uninterpretable for that part.

If we experience delays in the completion or termination of, any clinical trial of AQX-1125 or any future product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and could shorten any periods during which we may have the exclusive right to

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commercialize our product candidates or allow our competitors to bring products to market before we do, and jeopardize our ability to commence product sales, which would impair our ability to generate revenues and may harm our business, results of operations, financial condition and cash flows and future prospects. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of AQX-1125 or our future product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for AQX-1125 or our future product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that neither AQX-1125 nor any future product candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement over the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- disagreement over our interpretation of data from preclinical studies or clinical trials;
- disagreement over whether to accept efficacy results from clinical trial sites outside the United States where the standard of care is potentially different from that in the United States;
- the insufficiency of data collected from clinical trials of AQX-1125 or our future product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or

changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. Even if we do obtain regulatory approval, AQX-1125 or our future product candidates may be approved for fewer or more limited indications than we request, approval may be granted but contingent on the performance of costly post-marketing clinical trials, or approval with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if AQX-1125, or our future product candidate, produce undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may restrict distribution of our products and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have had limited interactions with the FDA and have not discussed our proposed regulatory approval strategy with the FDA. Even if we believe our current or planned clinical trials are successful, the FDA may not agree that our completed clinical trials provide adequate data on the safety or efficacy of AQX-1125 or our future product candidates to permit us to proceed to Phase 3 clinical trials. Approval by comparable foreign regulatory authorities does not ensure approval by the FDA and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and even if we file we may not receive the necessary approvals to commercialize our products in any market.

We are conducting, and may in the future conduct, clinical trials for AQX-1125 or any future product candidates in sites outside the United States and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient

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population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our Leadership and Flagship clinical trials conducted outside of the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of AQX-1125 or any future product candidates.

AQX-1125 or our future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by AQX-1125 or our future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. For example, even though AQX-1125 administered orally has generally been well tolerated by patients in our earlier-stage clinical trials, in our animal toxicity studies certain side-effects, including severe ulcerations to the gastrointestinal tract of dogs and adverse effects to the ocular lens of some animals occurred. There can be no assurance that these toxicities in animals will not occur in humans. If these toxicities do occur in our future clinical trials they could cause delay or even discontinuance of further development of AQX-1125 or future product candidates, which would impair our ability to generate revenues and would have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

To date, the most common side-effect of AQX-1125 noted in clinical trials is mild gastrointestinal upset including mild diarrhea, nausea and gastric pain. In the Flagship trial, there have been patients requiring hospitalization for exacerbations of COPD, as expected, which have been reported as serious adverse events. Exacerbations of COPD requiring hospitalization are anticipated in the Flagship trial of unstable COPD patients. There can be no assurance that side-effects from AQX-1125 in future clinical trials will not prompt the discontinued development of AQX-1125 or future product candidates. As a result of these side effects or further safety or toxicity issues that we may experience in our clinical trials in the future, we may not receive approval to market AQX-1125 or any future product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Additionally, if AQX-1125 or any of our future product candidates receives marketing approval, and we, or others, later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;

regulatory authorities may withdraw their approvals of such product;

regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;

the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;

the FDA may require the establishment or modification of REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;

we may be required to change the way the product is administered or conduct additional clinical trials;

we could be sued and held liable for harm caused to subjects or patients

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if AQX-1125 or our future product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for AQX-1125 or a future product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable

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foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of AQX-1125 or any future product candidate, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for AQX-1125, if it achieves marketing approval, may include restrictions on use.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose restrictions on the marketing or manufacturing of the product candidates;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or any future collaborator to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize AQX-1125 or any future product candidates and generate revenue.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product s approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the DOJ, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

In the United States, engaging in impermissible promotion of our future products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual may share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect our business, results of operations, financial condition and cash flows and future prospects.

Existing government regulations may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of AQX-1125 or any future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and/or be subject to fines or enhanced government oversight and reporting obligations, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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Failure to obtain regulatory approval in international jurisdictions would prevent AQX-1125 or any future product candidates from being marketed outside the United States.

In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of AQX-1125 or any of our future product candidates by regulatory authorities in the European Union or another jurisdiction, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of, and commercialization of, AQX-1125 or our future product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of AQX-1125 or our future product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for certain pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drugs prescribed to the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of outpatient prescription drugs that will be covered in any therapeutic class. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare & Medicaid Services, the agency that administers the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of, and reimbursement for, any approved products, which in turn could affect the price we can receive for those products. While the Medicare Modernization Act and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in establishing their own coverage polices and reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, in an effort to, among other things, broaden

access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act, among other things, also expanded manufacturers rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also revised the definition of AMP for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates to states. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the Affordable Care Act, and any of its implementing regulations, the new law has the potential to: substantially change healthcare financing and delivery by both governmental and private insurers; continue the pressure on pharmaceutical pricing, especially under the Medicare program; and increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select

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Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of AQX-1125 or our future product candidates, if any, may be.

In the United States, the European Union and other potentially significant markets for AQX-1125 and our future product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional coverage, pricing and reimbursement controls in the European Union will put additional pressure on product coverage, pricing, reimbursement and utilization, which may adversely affect our business, results of operations, financial condition and cash flows and future prospects. These pressures can arise from various sources, including but not limited to, rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and Canada and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States and Canada, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We must also comply with U.S. laws applicable to the foreign operations of U.S. businesses and individuals, such as the Foreign Corrupt Practices Act, or FCPA, and Canadian laws applicable to the foreign operations of Canadian businesses and individuals, such as the Corruption of Foreign Public Officials Act, or CFPOA. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of

influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved.

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Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA s accounting provisions.

The CFPOA prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Furthermore, a company may be found liable for violations by not only its employees, but also by its third-party agents. Any failure to comply with the CFPOA, as well as applicable laws and regulations in foreign jurisdictions, could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions, which may have a material adverse impact on us and our share price.

Even if we are able to commercialize AQX-1125 or our future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use AQX-1125, or our future product candidates, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement

will be obtained or applied consistently. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We have never marketed a drug before, and if we are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to generate any revenue.

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical drug products and the cost of establishing and maintaining such an infrastructure may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

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AQX-1125 and our future product candidates, if approved, may not achieve adequate market acceptance among physicians, patients, and healthcare payors and others in the medical community necessary for commercial success.

Even if we obtain regulatory approval for AQX-1125 or any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians and patients of the product candidate as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including a product candidate s use outside the approved indications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;

the effectiveness of our sales and marketing efforts and those of our collaborators; and

unfavorable publicity relating to the product candidate.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, or healthcare payors, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Our relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors are and will be subject, directly and indirectly, to applicable anti-kickback, fraud and abuse, privacy, transparency and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal and administrative sanctions, civil penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings and the curtailment or restructuring of our operations.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our future arrangements with third-party payors and customers who are in a position to purchase, recommend and/or prescribe our product candidates for which we obtain marketing approval. These broadly applicable fraud and abuse and other healthcare laws and regulations may constrain our future business or financial arrangements and relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities, including our marketing practices, educational programs and pricing policies. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

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

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

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g. public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to

healthcare matters;

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HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers;

the federal Physician Payment Sunshine Act, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other transfers of value to such physician owners and their immediate family members; and

analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Recent healthcare reform legislation has also strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, we expect there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for AQX-1125 or any future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and

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abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations, financial condition and cash flows from future prospects, including the imposition of significant fines or other sanctions.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate, AQX-1125, and will face competition with respect to any future product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing AQX-1125 or our future product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

As a result of these factors, our competitors may obtain regulatory approval of their products before we do, which will limit our ability to develop or commercialize AQX-1125 or any of our future product candidates. Although there are no approved therapies that specifically target SHIP1, there are currently approved therapies for treating the same diseases or indications for which our product candidates may be useful. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

If AQX-1125, our current product candidate, were approved as treatment of COPD, it could face competition from currently approved and marketed products, including GlaxoSmithKline (fluticasone/salmeterol LABA/ICS combination (Advair) and umeclidinium, vilanterol LAMA (Anoro)), GlaxoSmithKline/Theravance (LABA/ICS combination fluticasone/vilanterol (Breo Ellipta)), Boehringer Ingelheim/Pfizer (tiotropium LAMA (Spiriva)), Boehringer Ingelheim (olodaterol LABA), AstraZeneca (formoterol/budesonide LABA/ICS (Symbicort)), Almirall SA (AMA aclidinium (Tudorza Pressair), and Novartis AG (LABA indacterol (Onbrez Breezhaler) and glycopyrrolate/indacaterol LABA/LAMA (Ultibro Breezhaler)) and Takeda Pharmaceuticals International GmbH (Phosphodiesterase-4 (PDE4) inhibitor, Roflumilast). If AQX-1125 were approved for the treatment of BPS/IC, it could face competition from currently approved and marketed products, including Janssen Pharmaceuticals Inc. s pentosan polysulfate sodium, marketed in the United States as Elmiron, which is now generic. Also, we believe that

Gilead Sciences, Inc., Amgen Inc., and TG Therapeutics, Inc. are developing drugs that target the delta and/or gamma isoforms of PI3K. In addition, many companies are developing product candidates directed to disease targets in the fields of COPD, BPS/IC and AD, including in the specific diseases for which we are currently developing AQX-1125, or for which we may develop AQX-1125 or other SHIP1 activators in the future. Such companies include Pfizer, AbbVie, Urigen, TARIS, Allergan, Galderma and Afferent.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of AQX-1125, including relative to marketed products and product candidates in development by third parties;
- the time it takes for AQX-1125 or any of our future product candidates to complete clinical development and receive marketing approval;
- the ability to commercialize AQX-1125 and future product candidates that receive regulatory approval;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the ability to manufacture commercial quantities of AQX-1125 and future product candidates that receive regulatory approval; and
- acceptance of AQX-1125 and future product candidates that receive regulatory approval by physicians and other healthcare providers.

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Our failure to successfully identify, acquire, develop and commercialize additional product candidates or approved products other than AQX-1125 could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our most advanced product candidate, AQX-1125, a key element of our growth strategy is to acquire, develop and/or market additional products and product candidates. All of our other potential product candidates remain in the discovery and preclinical study stages. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists 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 and acquire promising pharmaceutical product candidates and products. 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 have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, 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. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign 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 regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of AQX-1125 and any future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

significant costs to defend the related litigation;

substantial monetary awards to trial subjects or patients;

loss of revenue;

diversion of management and scientific resources from our business operations; and

the inability to commercialize our product candidates.

We currently have obtained product liability insurance coverage, which is limited to $5 million per occurrence and $5 million in the aggregate. This coverage may not be adequate to cover all liabilities that we may incur. Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for AQX-1125 or our future product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We will need to expand our operations and grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2014, we had 24 employees. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, scientific, and financial headcount and other resources. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;

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identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;

managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

manage additional relationships with various strategic partners, suppliers and other third parties;

improving our managerial, development, operational and finance reporting systems and procedures; and

expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to attract, retain and motivate qualified personnel.

We may not be able to attract or retain qualified managerial, operational, sales, marketing, scientific and financial personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of our executive officers. If we lose one or more of our executive officers or key employees, particularly our President, Chief Executive Officer and Chairman of the Board, David Main, our Vice President, Technical Operations, Lloyd Mackenzie, our Chief Financial Officer and Vice President, Finance, Kamran Alam, our Chief Medical Officer and Senior Vice President, Clinical Development, Stephen Shrewsbury, M.B., ChB., or our Vice President, Global Regulatory Affairs and Quality Assurance, David C. Mitchell, our ability to implement our business strategy successfully could be seriously harmed. Replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. Many of the other pharmaceutical companies that we compete with for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. Further, we do not maintain key person insurance for any of our executives or other employees. Our failure to retain key personnel could impede the achievement of our research, development and commercialization objectives.

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our business, results of operations, financial condition and cash flows and future prospects.

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit

with AQX-1125 or our future product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our existing stockholders percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
- the failure to discover undisclosed liabilities of the acquired asset or company;
- diversion of management s attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

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Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of AQX-1125 or our future product candidates could be delayed.

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

We are subject to numerous environmental, health and safety laws and regulations in the United States and Canada, including, as a result of our subleased laboratory space, those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash

flows from future prospects.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, this could substantially harm our business because we may not be able to obtain regulatory approval for or commercialize AQX-1125 or our future product candidates in a timely manner or at all.

We have extensively relied upon and plan to continue to extensively rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We

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cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize AQX-1125 or our future product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and cash flows and future prospects.

If our relationships with CROs terminate, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with our third-party CROs terminate, we could experience a significant delay in identifying, qualifying and managing performance of a comparable third-party service provider, which could adversely affect our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. We may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

We have no experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. As a result, we are dependent on third-party manufacturers for the manufacture of AQX-1125, as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of AQX-1125 or our future product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on a single source contract manufacturing organization, or CMO, for the chemical manufacture of active pharmaceutical ingredient for AQX-1125, and another CMO for the production of AQX-1125 final product formulation in a gelatin capsule and

packaging for Phase 2 clinical trials. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. We have not yet identified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. We may encounter technical difficulties or delays in the transfer of AQX-1125 manufacturing on a commercial scale to additional third-party manufacturers. We may be unable to enter into agreements for commercial supply with third party manufacturers, or may be unable to do so on acceptable terms. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products

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that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates and could cause us to incur higher costs and prevent us from commercializing our product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, our competitive position could be harmed.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our discovered or licensed compounds will result in the issuance of patents that protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us

or our future potential licensor(s) to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We could be required to incur significant expenses to strengthen our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position.

The patent prosecution process is expensive and time-consuming, and we or our future potential licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future potential licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or

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shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a first to file system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office, or the USPTO, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration 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, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee

or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our future potential licensors fail to maintain the patents and patent applications covering AQX-1125 or our future product candidates, our competitive position would be adversely affected.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee s former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in prosecuting or defending any such claims, in addition

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to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CMOs, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA s disclosure policies may change in the future, if at all.

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

Filing, prosecuting and defending patents on AQX-1125 and our future product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors or collaborators patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors or collaborators efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have.

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

Others may be able to make compounds that are the same as or similar to AQX-1125 or our future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.

We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.

It is possible that our pending patent applications will not lead to issued patents.

Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

We may not develop additional proprietary technologies that are patentable.

The patents of others may have an adverse effect on our business.

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, volatile for the foreseeable future. For example, in the year ended December 31, 2014, our common stock s daily closing price on the NASDAQ Global Market has ranged from a low of $5.50 to a high of $14.35. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this Risk Factors section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials, including both safety and efficacy, of AQX-1125 or any of our future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to AQX-1125 or any of our future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

announcement or expectation of additional financing efforts;

sales of our common stock by us, our insiders or our other stockholders;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors; and

general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and 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.

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Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in this Risk Factors section and elsewhere in this report, could have a dramatic and material adverse impact on the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and will continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management s attention from other business concerns, which could seriously harm our business.

Our principal stockholders, directors and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together beneficially own a significant percentage of our outstanding voting stock. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors and adversely affect the market price of our common stock or make it more difficult to raise capital as and when we need it.

We are an emerging growth company as that term is used in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and exemptions from any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor s report on the financial statements. We currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us under the JOBS Act, so long as we qualify as an emerging growth company. For example, so long as we qualify as an emerging growth company, we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be

for up to five years.

Because of the exemptions from various reporting requirements provided to us as an emerging growth company we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our business, results of operations, financial condition and cash flows and future prospects may be materially and adversely affected.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our business, results of operations, financial condition and cash flows and future prospects, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10-K for the year ending December 31, 2015, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or

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combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In connection with the audit of the consolidated and combined financial statements of Aquinox USA and AQXP Canada as of December 31, 2014 and December 31, 2013, and for the years then ended, we identified certain significant deficiencies in our internal controls over financial reporting. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of our financial reporting, including the audit committee of the board of directors. During the evaluation and testing process, if we fail to remediate the significant deficiencies identified, fail to identify and to remediate any significant deficiencies or material weaknesses that may be identified in the future, or encounter problems or delays in the implementation of internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

As a public company, we have incurred and will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and NASDAQ Stock Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. We estimate that we will incur approximately $2.0 to $3.0 million of incremental costs per year associated with being a publicly traded company, although it is possible that our actual incremental costs will be higher than we currently estimate. The increased costs will increase our combined net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of certain shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our 2014 Equity Incentive Plan, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. Future option grants and issuances of common stock under our 2014 Equity Incentive Plan may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that:

permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder s notice;

not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of

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directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, or our business. If one or more of the securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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Item 1B. Unresolved Staff Comments.
None.

Item 2. Properties.
Our corporate headquarters are located in Vancouver, Canada, where we lease approximately 5,200 square feet of office space pursuant to a lease agreement that expires on March 31, 2016. This facility houses our research, clinical, regulatory, commercial and administrative personnel. During 2014, we also leased approximately 15,000 square feet of office and laboratory space in Richmond, Canada, pursuant to a lease agreement that was terminated on December 31, 2014 as we elected to alter our strategy to greater reliance on sub-contracting of activities requiring laboratory facilities.

We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 3. Legal Proceedings.
We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.
None.

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PART II

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

Price Range of Our Common Stock

Our common stock is traded on The NASDAQ Global Market under the symbol AQXP. As of March 12, 2015, there were 10,717,128 shares of our common stock outstanding, which were held by approximately 37 holders of record of our common stock, including The Depository Trust Company, which holds shares of our common stock on behalf of an indeterminate number of beneficial owners. As of March 12, 2015, the closing price of our common stock as reported on The NASDAQ Global Market was $12.03 per share.

The following table sets forth, for the periods indicated, the reported high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

	High	Low
2014		
First Quarter (beginning March 7, 2014)	$ 14.35	$ 11.26
Second Quarter	13.35	8.26
Third Quarter	9.29	6.22
Fourth Quarter	8.60	5.50
2015		
First Quarter (through March 12, 2015)	$ 12.03	$ 7.63

Dividend Policy

We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

Stock Performance Graph

Our common stock began trading on The NASDAQ Global Market on March 7, 2014. The graph and table below shows the cumulative total return to our stockholders during the period from March 7, 2014 through December 31, 2014 in comparison to the cumulative return on the NASDAQ Composite Index and the NASDAQ Biotechnology Index during that same period. The results assume that $100 was invested on March 7, 2014 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

For the period March 7, 2014 to December 31, 2014	
Aquinox Pharmaceuticals, Inc.	$ 62.76
NASDAQ Composite Index	$ 109.22

NASDAQ Biotechnology Index	$ 117.27

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This information under Stock Performance Graph is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Use of Proceeds

On March 6, 2014, our registration statement on Form S-1 (Registration No. 333-193615) was declared effective for our IPO. We issued 4,830,000 common shares for gross proceeds of $53.1 million, less offering cost of $5.3 million, resulting in net proceeds of $47.8 million. We have been and will continue to be using the proceeds of this offering to conduct Phase 2 clinical trials to evaluate AQX-1125 as a potential treatment in indications beyond COPD and BPS/IC, to conduct additional toxicology studies, and large batch manufacturing and process development related to AQX-1125, to advance one or more of our next generation SHIP1 activator compounds through preclinical development, and to fund working capital, capital expenditures and other general corporate purposes which may include the acquisition or licensing of future product candidates, technologies, other assets or businesses. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated March 6, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. As of December 31, 2014, we had used approximately $6.8 million of the proceeds from our IPO.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our consolidated financial statements and notes to our consolidated financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated and Combined Statements of Operations data for the years ended December 31, 2014, 2013 and 2012 and Consolidated and Combined Balance Sheet data as of December 31, 2014, 2013 and 2012 have been derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

Consolidated and Combined Statement of Operations Data

	Year Ended December 31, 2014	Year Ended December 31, 2013	Year Ended December 31, 2012
Operating expenses:			
Research and development	$ 18,079,262	$ 7,598,750	$ 6,045,395
General and administrative	4,296,447	1,776,905	1,635,623
Total operating expenses	$ 22,375,709	$ 9,375,655	$ 7,681,018
Net loss	$ (24,027,016)	$ (8,729,371)	$ (7,714,198)
Total loss attributable to common stockholders	$ (23,821,276)	$ (14,941,829)	$ (12,137,948)
Net loss per common stock - basic and diluted	$ (2.75)	$ (49.52)	$ (40.23)
Basic and diluted weighted average common stock outstanding	8,667,387	301,745	301,745

Consolidated and Combined Balance Sheet Data

	December 31, 2014	December 31, 2013	December 31, 2012
Cash, cash equivalents and short-term investments	$ 39,097,306	$ 13,826,992	$ 2,000,539
Working capital	34,098,451	12,676,246	1,678,695
Total assets	41,422,947	15,649,106	2,341,990
Warrant liabilities	72,341	221,320	
Redemption option on preferred stock		800,206	
Accrued tax payable on preferred stock		1,797,412	1,059,487

Bank loan		2,286,489	
Redeemable convertible preferred stock		73,858,722	51,975,238
Total stockholders equity (deficit)	36,147,298	(65,693,708)	(51,101,207)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 41,422,947	$ 15,649,106	$ 2,341,990

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The following table contains selected unaudited financial data for each quarter of 2014 and 2013. The unaudited information should be read in conjunction with our financial statements and related notes included elsewhere in this report. We believe that the following unaudited information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Quarterly Financial Data

	THREE MONTHS ENDED			
2014	**MARCH 31**	**JUNE 30**	**SEPTEMBER 30**	**DECEMBER 31**
Total operating expenses	$ 2,614,338	$ 5,632,393	$ 6,309,885	$ 7,819,093
Net loss	$ (4,227,678)	$ (5,424,759)	$ (6,284,080)	$ (8,090,499)
Net loss attributable to common stockholders	$ (4,021,937)	$ (5,424,759)	$ (6,284,080)	$ (8,090,499)
Net loss per common stock basic and diluted	$ (1.28)	$ (0.51)	$ (0.59)	$ (0.76)

2013	**MARCH 31**	**JUNE 30**	**SEPTEMBER 30**	**DECEMBER 31**
Total operating expenses	$ 996,832	$ 1,616,860	$ 3,417,068	$ 3,344,895
Net loss	$ (1,010,267)	$ (811,502)	$ (3,367,487)	$ (3,540,115)
Net loss attributable to common stockholders	$ (2,558,530)	$ (2,382,104)	$ (4,720,230)	$ (5,280,962)
Net loss per common stock basic and diluted	$ (8.48)	$ (7.89)	$ (15.64)	$ (17.50)

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

Forward-Looking Statements

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs, and involve risks and uncertainties. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. Our primary focus is anti-inflammatory product candidates targeting SHIP1, which is a key regulator of an important cellular signaling pathway in immune cells, known as the PI3K pathway. Our lead product candidate, AQX-1125, is a small molecule activator of SHIP1 suitable for oral, once daily dosing. Having successfully completed multiple preclinical studies and clinical trials with AQX-1125, we are now advancing through Phase 2 development in several initial indications. We have successfully completed three clinical trials with AQX-1125 dosed as a once daily oral product, with over 100 subjects having received AQX-1125 to date. We are currently investigating AQX-1125 in three Phase 2 clinical trials, one in Chronic Obstructive Pulmonary Disease (COPD), one in Bladder Pain Syndrome/Interstitial Cystitis (BPS/IC), and one in Atopic Dermatitis (AD). COPD, BPS/IC and severe forms of AD are debilitating chronic inflammatory diseases affecting millions of people worldwide. For AQX-1125, we retain full worldwide rights and hold patents with terms through at least 2024.

We use a proprietary screening approach to discover new drug candidates that selectively target SHIP1 to modulate activated immune cells while minimizing their toxicity to normal cells. Our intellectual property covers SHIP1 as a target, the C2 binding domain for screening and the composition of matter for our compounds.

We have an extensive chemical library and several candidate lead compounds that target SHIP1. These compounds have both similar and distinct properties from AQX-1125. We believe AQX-1125 is the only SHIP1 activator currently in clinical trials and that no SHIP1 activator has yet received marketing approval as a treatment for disease in humans.

We commenced operations as 6175813 Canada Inc., a corporation formed in December 2003 under the Canada Business Corporations Act. In May 2014, after a corporate restructuring, we changed the name of such entity to Aquinox Pharmaceuticals (Canada) Inc. (AQXP Canada). We incorporated Aquinox Pharmaceuticals (USA) Inc., a corporation under the laws of the State of Delaware, in May 2007. We subsequently changed the name of this corporation in January 2014 to Aquinox Pharmaceuticals, Inc. (Aquinox USA). Upon the completion of our initial public offering in March 2014, AQXP Canada became a wholly owned subsidiary of Aquinox USA,

Since commencing operations, we have dedicated a significant portion of our resources to development efforts for our clinical-stage product candidate AQX-1125. We anticipate that we will continue to incur significant operating expenses related to research and development as we continue to advance our preclinical programs and our clinical-stage product candidates. We have funded our operations primarily through the sale of common stock and preferred stock and through debt financing. As of December 31, 2014, we had $41.1 million in cash, cash equivalents, short and long-term investments in liquid, high-quality securities.

Since inception, we have incurred significant operating losses. Our net losses for the year ended December 31, 2014 were $24.0 million. This compared to $8.7 million for the year ended December 31, 2013. As of December 31, 2014, we had an accumulated deficit of $89.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, AQX-1125 and any future product candidates we advance to clinical development. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. For example, we do not currently have the infrastructure for the sales, marketing, manufacture and distribution of any products. We may enter into licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories, but have not currently entered into any such arrangements. To develop a commercial infrastructure, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty of marketing approval.

As a result of the requirements of being a public company, we have incurred and expect to incur additional costs associated with operating as a public company. Unless and until we generate sufficient revenue to be profitable, we will seek to fund our operations primarily through public or private equity or debt financings or other sources. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

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Results of Operations

Revenue

To date, we have not generated any revenue. In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and royalties from the sale of products developed under licenses of our intellectual property.

Operating Expenses

The following table summarizes our operating expenses for the years ended December 31, 2014, 2013 and 2012:

	YEAR ENDED DECEMBER 31,		
	2014	**2013**	**2012**
Research and development	$ 18,079,262	$ 7,598,750	$ 6,045,395
General and administrative	4,296,447	1,776,905	1,635,623
Total operating expenses	$ 22,375,709	$ 9,375,655	$ 7,681,018

Research and Development Expenses

Research and development activities are central to our business model. Since the completion of early-stage lead compound identification and screening in 2012, we began to focus our resources on clinical development and on outsourced research activities. Our research and development expenses consist primarily of costs incurred for the development of AQX-1125 and other future product candidates. Research and development expenses include:

costs associated with research, development and regulatory activities;

employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;

expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;

the cost of acquiring and manufacturing our products, for preclinical studies and clinical trials;

cost incurred in relation to purchase of technology licenses and patent rights; and

facilities, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, amortization of equipment and leasehold improvements, insurance and supplies.

Research and development costs are expensed as incurred. License fees and milestone payments we make related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our main clinical activities are described as follows:

Leadership Trial

In July 2013, we began dosing patients in a Phase 2 clinical trial of AQX-1125 for the treatment of BPS/IC. BPS/IC is a chronic inflammatory bladder disease characterized by bladder pain and increased urinary urgency and/or frequency. Our clinical trial, known as the Leadership trial, is a double-blind, placebo-controlled, Phase 2 clinical trial investigating the ability of AQX-1125 to reduce pain and urinary symptoms in approximately 70 female patients with BPS/IC. The primary objective of this trial is to measure the difference in the change from baseline in the mean daily bladder pain score based on an 11-point numeric rating scale (NRS) at six weeks recorded by eDiary. The trial is being conducted at community and academic sites in Canada and the United States. We have now completed enrolment for the Leadership trial. With 69 patients randomized to date and a higher completion rate than forecast for the trial, we have met our enrolment objectives. Top-line data is expected near mid-year 2015.

Flagship Trial

In December 2013, we began dosing patients in a Phase 2 clinical trial of AQX-1125 for the treatment of exacerbations of COPD. COPD is a lung disease frequently associated with cigarette smoking and air pollution and is characterized by progressive loss of lung function and chronic inflammation of the airways. Our clinical trial, known as the Flagship trial, is a multinational, double-blind, placebo-controlled, Phase 2 clinical trial investigating the ability of AQX-1125 to reduce the effects of exacerbations in 400 unstable patients with moderate to severe COPD who have experienced a recent exacerbation and at least two other exacerbations in the prior 18 months. The primary endpoint is the change in the severity, duration and reoccurrence of exacerbations in patients treated with AQX-1125 versus placebo, as measured by EXACT-PRO, a patient-reported outcome tool that measures symptoms. The Flagship trial is being conducted at outpatient clinics in Europe, Australia, New Zealand and the United States. On February 2, 2015, we announced the completion of enrolment for this clinical trial. Top-line data is expected near mid-year 2015.

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Kinship Trial

In December 2014, we began dosing patients in a Phase 2 clinical trial of AQX-1125 for the treatment of AD. AD is an inflammatory, relapsing and itchy skin disorder. It is often chronic in nature. Our clinical trial, known as the Kinship trial, is being conducted at clinical research centers in Canada as a randomized, double-blind, multicenter, placebo-controlled Phase 2 trial evaluating the efficacy and safety of AQX-1125 in approximately 50 adult patients with mild to moderate AD. The Kinship trial s primary endpoint is change from baseline in Total Lesion Symptom Score (TLSS) after 12 weeks of treatment.

The following table summarizes the nature of our research and development expenses for the years ended December 31, 2014, 2013 and 2012:

	YEAR ENDED DECEMBER 31,		
	2014	**2013**	**2012**
Clinical development	$ 9,820,270	$ 3,052,708	$ 1,993,341
Personnel related	1,611,153	1,373,587	1,834,172
Manufacture and formulation	3,720,766	1,962,396	174,114
Preclinical research	1,820,701	154,246	871,755
Facility and overhead	840,377	844,520	974,362
Consulting	25,031	36,633	21,990
Stock-based compensation	240,964	174,660	175,661
Total research and development expenses	$ 18,079,262	$ 7,598,750	$ 6,045,395

Research and development expenses for the year ended December 31, 2014 increased to $18.1 million due to increased clinical activity as described above. This compared to $7.6 million for the year ended December 31, 2013 when there was significantly less clinical activities as the Leadership trial and Flagship trial did not begin dosing until July 2013 and December 2013, respectively. During the year ended December 31, 2012, we were engaged in early stage lead compound identification and screening activities which resulted in lower research and development expenses of $6.0 million. We expect our future research and development expenses to continue to increase as our clinical trials progress.

It is difficult to determine with certainty the duration and completion costs of our clinical trials of AQX-1125 and any of our future product candidates we may advance, or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each

program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate s commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for executive and other administrative personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, gain or loss on disposal of equipment, communication expenses and professional fees for legal, patent review, consulting and accounting services.

For the year ended December 31, 2014, general and administrative expenses of $4.3 million were higher compared to $1.8 million for the year ended December 31, 2013. The increase is the result of additional costs associated with being a public company as we completed our IPO in March 2014. This included, among other expenses, increased costs for insurance, costs related to the hiring of additional personnel and outside consultants and increased travel. General and administrative expenses for the year ended December 31, 2013 of $1.8 million were slightly higher than the $1.6 million incurred for the year ended December 31, 2012 due to increase in personnel costs.

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Bank charges and financing costs

Bank charges and financing costs consist of bank loan interest, warrant discount amortization and normal course bank charges. For the year ended December 31, 2014, our bank charges and financing costs were $0.5 million. This compared to less than $0.1 million for the year ended December 31, 2013. The increase was due to early repayment of the term loan with Silicon Valley Bank, or SVB, entered into in October 2013 and repaid in March 2014 resulting in early repayment penalty and fees of $0.1 million and accretion of warrant discount and deferred costs of $0.3 million.

Bank charges and financing costs for the year ended December 31, 2013 were higher compared to the small amount incurred for the year ended December 31, 2012 due to interest expense on the term loan with SVB entered into in October 2013.

Change in fair value of derivative liabilities

Our derivative liabilities comprised our convertible preferred stock warrants and redemption options. Derivative liabilities are re-measured at each balance sheet date with the corresponding change recorded within change in fair value of derivative liabilities. In March 2014, in connection with our IPO, we converted all our preferred stock to common stock in accordance to the terms of our preferred stock and extinguished derivative liabilities related to our preferred stock. As a result, the change in fair value for the year ended December 31, 2014 of $0.9 million was primarily due to the extinguishment of the liabilities associated with our preferred stock described above. This compared to $1.0 million for the year ended December 31, 2013 when the change in fair value was associated with our preferred stock derivative liabilities and preferred stock warrant derivative liabilities. We did not have any derivative liabilities in 2012.

Amortization and extinguishment of remaining discount on preferred stock

Amortization and extinguishment of discount on preferred stock for the year ended December 31, 2014 was $1.9 million compared to $0.4 million for the year ended December 31, 2013. The increase was due to the conversion of all our preferred stock to common stock in March 2014, resulting in the extinguishment of all remaining discount on our preferred stock.

Amortization on preferred stock was higher for the year ended December 31, 2013 compared to less than $0.1 million for the year ended December 31, 2012 due to additional amortization resulting from the issuance of Series C preferred stock in March 2013.

Other income (expenses)

Other income (expenses) includes primarily interest income and foreign exchange gains/losses. For the year ended December 31, 2014, we had other expenses of $0.3 million, compared to other income of $0.1 million for the year ended December 31, 2013. The expenses in 2014 were primarily the results of foreign exchange losses on our Euro and Canadian dollar holdings as both the Euro and the Canadian dollar declined significantly during 2014.

Other income for the year ended December 31, 2013 were higher than other income of $0.1 million for the year ended December 31, 2012 as a result of gain on sale of equipment during 2013.

Liquidity and Capital Resources

From inception through December 31, 2014, we have received gross proceeds of $111.5 million from the issuance of common and preferred stock.

Since our inception, we have incurred net losses and negative cash flows from our operations. Our operating activities used $17.8 million, $7.9 million and $7.2 million of cash flows during the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of $89.4 million, working capital of $34.1 million and cash, cash equivalents, short and long-term investments of $41.1 million.

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Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2014, 2013 and 2012:

	YEAR ENDED DECEMBER 31,		
	2014	**2013**	**2012**
Net cash (used in) provided by:			
Operating activities	$ (17,805,565)	$ (7,938,014)	$ (7,232,202)
Investing activities	(23,573,322)	(2,640,524)	(6,447)
Financing activities	45,278,582	19,584,391	
Increase (decrease) in cash and cash equivalents	$ 3,899,695	$ 9,005,853	$ (7,238,649)

Net cash used in operating activities

The increase in cash used in operating activities for the year ended December 31, 2014 compared to the year ended December 31, 2013 was driven by an increase in clinical development expenses as a result of the two large Phase 2 clinical trials, the Leadership and Flagship trials, which were actively enrolling during 2014.

The increase in cash used in operating activities for the year ended December 31, 2013 compared to the year ended December 31, 2012 was due to the initiation of the Leadership and Flagship clinical trials during the second half of 2013 whereas during 2012 we were only engaged in early stage lead compound identification and screening activities.

Net cash (used in) provided by investing activities

Cash used in investing activities for the year ended December 31, 2014 consisted primarily of the purchase and sale of short and long-term investments as we invested the proceeds from our IPO into liquid, high quality securities in accordance to our treasury policy which focuses on the preservation of principal and maintenance of liquidity. During the year ended December 31, 2013, the net cash used in investing activities was primarily related to purchase of short-term guaranteed investment certificates, net of proceeds from the sale of lab equipment. During the year ended December 31, 2012, net cash used in investing activities involved purchase of fixed assets.

Net cash (used in) provided by financing activities

For the year ended December 31, 2014, net cash provided by financing activities was the result of the $53.1 million in proceeds from our IPO, offset by $5.3 million of offering costs and the repayment of a bank loan with SVB Bank for $2.6 million. For the year ended December 31, 2013, net cash provided by financing activities was the result of $18.0 million in proceeds from the issuance of Series C convertible preferred stock, offset by $0.6 million in share issue costs, and a $2.5 million loan from SVB bank, offset by $0.1 million in loan costs. There was no financing activity in 2012.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund our Phase 2 clinical trials

of AQX-1125, as well as our continuing preclinical activities. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. However, we anticipate that we will need to raise substantial financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a negative impact on our business, results of operations, financial condition and cash flows and future prospects. Our future capital requirements will depend on many factors, including:

the timing, receipt and amount of sales of, or royalties on, future approved products, if any;

the timing to completion and the results of our Phase 2 clinical trials;

the number and characteristics of any future product candidates we develop or may acquire;

the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, and conducting preclinical studies and clinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals for AQX-1125 or any future product candidates;

the cost of manufacturing AQX-1125 and our future product candidates and any products that may achieve regulatory approval;

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the cost of commercialization activities if AQX-1125 or any future product candidates are approved for sale, including marketing, sales and distribution costs;

our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the costs associated with being a public company; and

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

Please see Item 1A of this Annual Report titled Risk Factors for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2014[1]:

	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating lease obligations[2]	$ 217,296	$ 172,026	$ 45,270	$	$

1. Under the Asset Purchase Agreement dated August 19, 2009 between us and Biolipox AB, upon commencement by us of a Phase 3 trial of AQX-1125, a $3 million milestone payment will be due to Biolipox. We cannot predict the likelihood or the timing of any such payment.
2. AQXP Canada has a lease agreement for office space which commenced on January 1, 2014 and expires March 31, 2016. The dollar amounts shown in these columns reflect the US$ equivalent of the obligations. The amounts were converted to U.S. dollars from Canadian dollars using the average of the daily noon exchange rates for the year ended December 31, 2014. Applying this formula, Canadian $1.00 was equal to US$0.9054.

Purchase Commitments

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable purchase order basis.

Milestone, Royalty-Based and Other Commitments

On August 19, 2009, AQXP Canada entered into an asset purchase agreement with Biolipox AB of Sweden, or Biolipox, for the purchase of all assets, including patent rights and know-how, relating exclusively or principally to a compound library from which we ultimately identified and selected AQX-1125. Under the terms of the agreement, AQXP Canada paid Biolipox Canadian $50,000 immediately upon closing. An additional Canadian $250,000 by way of issuance of our common stock was made in June 2014 upon the first submission to the FDA of an IND for a compound from the acquired class. The terms of the agreement also require a one-time Canadian $3.0 million milestone payment upon the commitment of financial resources by the Board of Directors of AQXP Canada to advance AQX-1125 into a Phase 3 clinical trial. We will also be required to make certain other milestone payments totaling up to Canadian $1.5 million in the aggregate upon the first commercial sale of the first compound covered by the acquired patent rights (which we expect will be triggered by the first commercial sale of AQX-1125) in each of the United States, Europe and Japan. There are no royalty payments due under this agreement.

AQXP Canada entered into an exclusive license agreement with the University of British Columbia, or UBC, dated June 6, 2006, for certain patent rights and technology relating to small molecule compounds and pharmaceutical compositions as modulators of SHIP1 activity. This agreement was amended and restated on June 8, 2007, and subsequently amended in October 2006, June 2007, September 2008 and April 2010. This agreement will expire at the last to expire issued patent covering the licensed technology. The agreement will terminate automatically upon our insolvency or may be terminated by either party for material breach by the other party. The terms of the agreement required AQXP Canada to pay an initial license fee of Canadian $50,000, all of which was paid by the issuance of 5,208 common exchangeable shares of AQXP Canada. We do not currently have any product candidates under development that are covered by the agreement, nor have we sublicensed our rights under the licensed patents. However, if we develop products covered by the UBC technology in the future, we will be required to pay certain development and regulatory milestones up to an aggregate of Canadian $2.2 million for the first drug product developed under the license and up to Canadian $1.5 million for each subsequent drug product, which may be paid in cash or by issue of our shares. We must also pay UBC low single-digit royalties based on aggregate worldwide net sales of products covered by the licensed patents and a percentage of sublicensing revenue ranging from the low single digits to the mid double digits based on the stage of development at which such sublicense is granted. We are also required to reimburse costs incurred by UBC related to the prosecution and maintenance of the licensed patents, and to pay an annual license maintenance fee in the amount of Canadian $1,000.

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In May 2005, AQXP Canada entered into an assignment agreement, which was subsequently amended in December 2005 and March 2006, with the British Columbia Cancer Agency (BCCA) and StemCell Technologies, Inc. (STI), for the assignment to AQXP Canada of the 2002 exclusive license agreement between BCCA and STI to certain patents relating to technology relating to SHIP1. The license agreement between AQXP Canada and BCCA was amended and restated in August 2006 and June 2007. This agreement has subsequently been amended in June 2008 to revise the schedule of the technology licensed under this agreement, and further amended in February 2013. Pursuant to this agreement, as amended, BCCA has granted us an exclusive worldwide license to certain of its intellectual property relating to core SHIP1 technology, and screening of compounds for activity using SHIP1, including the C2 binding domain. The agreement is to expire at the later of 20 years from the effective date of the agreement or upon the expiration of the last patent covered by the license. The terms of the assignment agreement among STI, BCCA and AQXP Canada required AQXP Canada to pay an assignment license fee of Canadian $150,000, paid in stages beginning May 2005 and ending March 2006. We do not currently have any product candidates under development that are covered by the BCCA license agreement, nor have we sublicensed our rights under the licensed patents. However, if we develop products covered by the BCCA technology in the future, we will be required to pay BCCA low single-digit royalties based on aggregate worldwide net sales of products covered by the licensed patents, and if we sublicense any rights to the technology, a low double digit percentage of sublicensing revenue. We are also required to reimburse BCCA s patent costs incurred in relation to the licensed technology, and pay an annual maintenance fee in the amount of Canadian $5,000. Our license with BCCA will terminate automatically upon our insolvency, and may be terminated by either party for material breach by the other party.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of these financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued liabilities, stock-based compensation and derivative liabilities. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our consolidated and combined financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated and combined financial statements.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include, but are not limited to, employee-related expenses, including salaries and benefits, expenses incurred under agreements with CROs and investigative sites that conduct clinical trials and preclinical studies, the cost of acquiring, developing and manufacturing clinical trial materials, facilities, cost incurred in relation to purchase of technology licenses and patent rights, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, and other supplies and costs associated with clinical trials, preclinical activities, and regulatory operations.

Development costs are expensed in the period incurred unless we believe a development project meets generally accepted accounting criteria for deferral and amortization. No product development expenditures have been deferred to date. We record costs for certain development activities, such as clinical trials, based on our evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information

provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the combined financial statements as prepaid or accrued liabilities, as the case may be.

Warrant Liabilities and Preferred Stock Embedded Derivative Liabilities

We account for detachable warrants to purchase redeemable convertible preferred stock or common stock as liabilities as they are freestanding derivative financial instruments. The warrants are recorded as liabilities at fair value, estimated using a Black-Scholes option pricing model, and marked to market at each balance sheet date, with changes in the fair value of the derivative liabilities recorded in the statements of operations. We allocate the total consideration received for issuing preferred stock and warrants based on the relative fair value of each security at the date of issuance. This allocation results in a discount to the initial carrying amount of the preferred stock at the date of issuance. This discount is amortized over the life of the preferred stock and is recorded as amortization of discount of preferred stock in the statements of operations.

We also evaluate and account for conversion and redemption options embedded in convertible instruments as they can be free standing derivative financial instruments depending on certain criteria. If they are determined to be free standing derivative financial instruments, we record these as preferred stock embedded derivatives on their combined balance sheets at fair value with changes in the fair values of these derivatives recorded in the combined statements of operations.

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award will be recognized over the period during which services are provided in exchange for the award, generally the vesting period. All share-based payments to employees are recognized in the financial statements based upon their respective grant-date fair values.

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We estimate the fair value of options granted using the Black-Scholes option pricing model. This approximation uses assumptions regarding a number of inputs that required us to make significant estimates and judgments, including the expected forfeiture rate and expected term of the options. We also make decisions regarding the method of calculating the expected stock price volatility and the risk free interest rate used in the model. Since prior to our IPO in March 2014 our common stock was not publicly traded, the expected volatility assumption was based on industry peer information. Additionally, because we have no significant history to calculate the expected term, the simplified method calculation was used.

There is inherent uncertainty in our forecasts and projections and, if we had made different assumptions and estimates than those described previously, the amount of our stock-based compensation expense, net loss and net loss per share amounts could have been materially different.

Basic and Diluted Net Loss Per Share of Common Stock

We calculated net loss per share in accordance with ASC 260, *Earnings Per Share*. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents.

Potentially dilutive weighted average common stock equivalents totaled approximately 0.8 million, 6.2 million and 4.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods of net loss from continuing operations because of their anti-dilutive effect. Therefore, for the years ended December 31, 2014, 2013 and 2012, the weighted average shares used to calculate both basic and diluted loss per share are the same.

Recent Accounting Pronouncements

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period in response to the EITF consensus on Issue 13-D. ASU 2014-12 clarifies that entities should treat performance targets that can be met after the requisite service period of a share-based payment award as performance conditions that affect vesting. Therefore, an entity would not record compensation expense (measured as of the grant date without taking into account the effect of the performance target) related to an award for which transfer to the employee is contingent on the entity s satisfaction of a performance target until it becomes probable that the performance target will be met. ASU 2014-12 is effective for all entities for reporting periods (including interim periods) beginning after December 15, 2015. Early adoption is permitted. We do not anticipate a material impact to our financial position, results of operations or cash flows as a result of this change.

In June 2014, the FASB issued ASU 2014-10 Development Stage Entities , which resulted in the elimination of certain financial reporting requirements, including an amendment to variable interest entities guidance. The amendments remove all incremental financial reporting requirements from U.S. GAAP for development stage entities. The guidance removes the definition of a development stage entity and eliminates the requirements for development stage entities to: present inception-to-date amounts, label the financial statements as those of a development stage entity, disclose a description of the development stage activities in which the entity is engaged, and disclose the first year in which the entity is no longer a development stage entity. ASU 2014-10 is effective for annual reporting periods beginning after December 15, 2014, with early adoption permitted. On June 30, 2014, we elected to early adopt the provisions of ASU 2014-10. The adoption changed the presentation of certain financial statements and financial statement information, but did not have any other impact on our financial statements.

In August 2014, the FASB issued ASU 2014-15 Presentation of Financial Statements Going Concern , outlining management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern, along with the required disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016 with early adoption permitted. We do not anticipate a material impact to our financial statements as a result of this change.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Segment Reporting

We view our operations and manage our business in one segment, which is the identification and development of therapeutics in disease areas of inflammation and immuno-oncology.

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JOBS Act

In April 2012, the Jumpstart Our Business Startups Act (JOBS Act) was enacted. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. We are an emerging growth company, as defined in the JOBS Act and for as long as we remain an emerging growth company , we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions provide for, but are not limited to, relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, less extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and an extended transition period for complying with new or revised accounting standards. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (a) December 31, 2019 which is the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (b) when we have total annual gross revenue of at least $1.0 billion, (c) when we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (d) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. It is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and foreign currency exchange rates.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. As of December 31, 2014, we had holdings in U.S. government securities of $32.5 million. We have estimated the effect on

our investment portfolio of a hypothetical increase in interest rates by one percent (100 basis points) to be a reduction of $0.1 million in the fair value of our investment portfolio as of December 31, 2014.

Our exposure to foreign currency risk relates primarily to our Canadian operations, including payments we make to vendors and suppliers using foreign currencies and balances held in foreign currencies such as the Canadian dollar and the Euro. Foreign exchange losses for the year ended December 31, 2014 was $0.4 million due to significant decline in the Canadian dollar and Euro. For the years ended December 31, 2013 and 2012, our foreign exchange losses were less than $0.1 million. We currently do not hedge against foreign currency risk.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

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Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED AND COMBINED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Boards of Directors and Stockholders of

Aquinox Pharmaceuticals, Inc.

Vancouver, Canada

We have audited the accompanying consolidated and combined balance sheets of Aquinox Pharmaceuticals, Inc. and subsidiary (the Company) as of December 31, 2014 and 2013 and the related consolidated and combined statements of operations and comprehensive loss, convertible preferred stock and stockholders deficit, and cash flows for each of the years in the three-year period ended December 31, 2014. These financial statements and financial statement schedules are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedules based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated and combined financial statements present fairly, in all material respects, the financial position of Aquinox Pharmaceuticals, Inc. as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ Deloitte LLP

Vancouver, Canada

March 16, 2015

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AQUINOX PHARMACEUTICALS, INC.

Consolidated and combined balance sheets

(Expressed in U.S. dollars)

	DECEMBER 31, 2014	DECEMBER 31, 2013
Assets		
Current assets		
Cash and cash equivalents (Note 4)	$ 14,906,087	$ 11,006,392
Short-term investments (Note 14)	24,191,219	2,820,600
Accounts and other amounts receivable (Note 5)	65,447	27,946
Prepayments and deposits	139,006	63,975
Deferred offering costs		1,377,438
Total current assets	39,301,759	15,296,351
Property and equipment, net (Note 6)	104,694	75,465
Long-term investments (Note 14)	2,003,099	
Other	13,395	277,290
Total assets	$ 41,422,947	$ 15,649,106
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities (Note 7)	$ 5,203,308	$ 2,350,660
Current portion of bank loan (Note 8)		250,000
Other		19,445
Total current liabilities	5,203,308	2,620,105
Warrant liabilities (Note 10)	72,341	221,320
Redemption option on preferred stock (Note 14)		800,206
Accrued tax payable on preferred stock (Note 13)		1,797,412
Bank loan (Note 8)		2,036,489
Other		8,560
Total liabilities	$ 5,275,649	$ 7,484,092
Redeemable convertible preferred stock (Note 9)		
AQXP Canada, Series A exchangeable preferred shares, no par value - authorized unlimited as of December 31, 2014 (December 31, 2013 - unlimited); issued and outstanding, 0 as of December 31, 2014		13,329,639

(December 31, 2013 - 791,016)

Aquinox USA, Series A preferred stock, $0.000001 par value - authorized 0 as of December 31, 2014 (December 31, 2013 - 27,914,951); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 662,875)	11,157,138
AQXP Canada, Series B exchangeable preferred shares, no par value - authorized unlimited as of December 31, 2014 (December 31, 2013 - unlimited); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 793,617)	10,684,093

The accompanying notes form an integral part of these consolidated and combined financial statements

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	DECEMBER 31, 2014	DECEMBER 31, 2013
Aquinox USA, Series B preferred stock, $0.000001 par value - authorized 0 as of December 31, 2014 (December 31, 2013 - 45,454,535); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 1,573,797)		21,091,150
AQXP Canada, Series C exchangeable preferred shares, no par value - authorized unlimited as of December 31, 2014 (December 31, 2013 - unlimited); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 378,786)		3,830,961
Aquinox USA, Series C preferred stock, $0.000001 par value - authorized 0 as of December 31, 2014 (December 31, 2013 - 45,793,738); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 1,343,424)		13,765,741
Total redeemable convertible preferred stock	$	$ 73,858,722
Commitments and contingencies (Note 16)		
Stockholders equity (deficit)		
Share capital:		
Common stock (Note 11)		
Aquinox USA, common stock, $0.000001 par value - authorized, 50,000,000 as of December 31, 2014 (December 31, 2013 - 139,266,037); issued and outstanding, 10,695,108 as of December 31, 2014 (December 31, 2013 - 301,745)	11	
Preferred stock (Note 9)		
Aquinox USA, preferred stock, $0.000001 par value - authorized 5,000,000 as of December 31, 2014 (December 31, 2013 - 0); issued and outstanding, 0 as of December 31, 2014 (December 31, 2013 - 0)		
Additional paid-in capital	125,566,705	
Accumulated deficit	(89,415,563)	(65,693,708)
Accumulated other comprehensive income	(3,855)	
Total stockholders equity (deficit)	36,147,298	(65,693,708)
Total liabilities, redeemable convertible preferred stock, and stockholders equity (deficit)	$ 41,422,947	$ 15,649,106

The accompanying notes form an integral part of these consolidated and combined financial statements

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AQUINOX PHARMACEUTICALS, INC.

Consolidated and combined statements of operations and comprehensive loss

(Expressed in U.S. dollars)

	YEARS ENDED DECEMBER 31,		
	2014	**2013**	**2012**
Operating expenses			
Research and development	$ 18,079,262	$ 7,598,750	$ 6,045,395
General and administrative	4,296,447	1,776,905	1,635,623
Total operating expenses	22,375,709	9,375,655	7,681,018
Other income (expenses)			
Bank charges and financing costs	(461,587)	(42,923)	(9,470)
Change in fair value of derivative liabilities (Note 14)	949,185	961,641	
Amortization and extinguishment of remaining discount on preferred shares upon conversion of preferred shares	(1,884,237)	(386,420)	(45,448)
Other (expenses) income	(254,890)	108,942	64,032
	(1,651,529)	641,240	9,114
Net loss before income taxes	(24,027,238)	(8,734,415)	(7,671,904)
Income tax recovery (provision) (Note 13)	222	5,044	(42,294)
Net loss	$ (24,027,016)	$ (8,729,371)	$ (7,714,198)
Net loss per common stock basic and diluted (Note 12)	$ (2.75)	$ (49.52)	$ (40.23)
Basic and diluted weighted average common stock outstanding (Note 12)	8,667,387	301,745	301,745
Comprehensive loss:			
Net loss	$ (24,027,016)	$ (8,729,371)	$ (7,714,198)
Other comprehensive loss unrealized loss on securities available for sale	(3,855)		
Comprehensive loss	$ (24,030,871)	$ (8,729,371)	$ (7,714,198)

The accompanying notes form an integral part of these consolidated and combined financial statements

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AQUINOX PHARMACEUTICALS, INC.

Consolidated and combined statements of cash flows

(Expressed in U.S. dollars)

	YEARS ENDED DECEMBER 31,		
	2014	**2013**	**2012**
Operating activities			
Net loss	$ (24,027,016)	$ (8,729,371)	$ (7,714,198)
Non-cash items and reclassifications:			
Amortization	135,946	59,571	130,784
Financing costs	319,635	14,242	
Fees and penalty on bank loan repayment	100,000		
Gain on sale of equipment	(14,672)	(134,553)	
Amortization and extinguishment of remaining discount on preferred stock upon conversion of preferred stock	1,884,237	386,420	45,448
Change in fair value of derivative liabilities and gain on extinguishment of liabilities	(949,185)	(961,641)	
Stock-based compensation	854,188	349,321	351,322
Stock-based purchase of patent rights	186,356		
Foreign exchange loss and other	107,754		
Changes in operating assets and liabilities:			
Accounts and other amounts receivable	(37,502)	599	190,645
Prepayments and deposits	20,235	(102,792)	(12,076)
Accounts payable and accrued liabilities	3,614,459	1,180,190	(224,127)
Cash used in operating activities	(17,805,565)	(7,938,014)	(7,232,202)
Investing activities			
Purchase of investments	(36,474,883)	(2,820,600)	
Proceeds from maturity of investments	12,989,557		
Purchase of property and equipment	(113,890)	(11,741)	(6,447)
Sale of property and equipment	25,894	191,817	
Cash used in investing activities	(23,573,322)	(2,640,524)	(6,447)
Financing activities			
Bank loan (repayment) advance	(2,500,000)	2,500,000	
Loan costs, fees and penalty	(100,000)	(107,622)	
Preferred stock (redemption) issued	(590)	18,003,361	
Share issue costs		(223,910)	
Proceeds from exercise of stock options	460		
Initial public offering of common shares	53,130,000		
Initial public offering costs	(5,251,288)	(587,438)	

Cash provided by financing activities	45,278,582	19,584,391	
Increase in cash and cash equivalents during the period	3,899,695	9,005,853	(7,238,649)
Cash and cash equivalents, beginning of period	11,006,392	2,000,539	9,239,188
Cash and cash equivalents, end of period	$ 14,906,087	$ 11,006,392	$ 2,000,539
Supplemental disclosure of cash flow information:			
Interest paid	$ 31,719	$ 22,604	$
Interest received	$ 91,327	$ 26,316	$
Non-cash financing activities:			
Accrued offering costs	$	$ 790,000	$

The accompanying notes form an integral part of these consolidated and combined financial statements

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AQUINOX PHARMACEUTICALS, INC.

Consolidated and combined statement of convertible preferred stock and stockholders deficit

(Expressed in U.S. dollars)

	AQXP CANADA EXCHANGEABLE PREFERRED SHARES		AQUINOX USA PREFERRED STOCK		AQUINOX USA COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	T
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	CAPITAL	DEFICIT	LOSS	D
31,	1,584,633	$ 20,442,122	2,236,672	$ 27,458,826	301,745	$	$	$ (39,314,581)	$	$ (3
d on							351,322			
or on ock		1,647,432		2,212,708			(351,322)	(3,508,818)		(
or ace ock		72,296		96,406				(168,702)		
on ock		21,882		23,566						
tax ock								(394,908)		
d sive								(7,714,198)		(
31,	1,584,633	22,183,732	2,236,672	29,791,506	301,745			(51,101,207)		(5
ash,	378,786	3,950,228	1,325,753	13,825,822			7			
			17,671	415,431						
				(68,920)						

SA								
n or ada 357 k								
		(466,673)	(1,633,357)					
d on						349,321		
or on ock		2,036,438	3,315,021			(349,328)	(5,002,131)	(
or ace ock		45,754	77,320				(123,074)	
on ock		21,825	34,343					
on on ock		73,389	256,863					
tax ock							(737,925)	
d sive							(8,729,371)	(
31,	1,963,419	27,844,693	3,580,096	46,014,029	301,745		(65,693,708)	(6
d on						99,417		
or on ock		401,165		731,728		(99,417)	(1,033,476)	(
or ace		6,649		12,901			(19,550)	

ock									
on									
ock		4,187		6,467					
on on									
ock		16,623		58,300					
tax									
ock								(100,291)	
ment g nce nt									
e to of ock		551,334		1,686,549				1,458,478	
2014	1,963,419	28,824,651	3,580,096	48,509,974	301,745			(65,388,547)	(6
of ock x on	(1,963,419)	(28,824,651)	(3,580,096)	(48,509,974)	5,543,515	7	77,333,844		7
ock, sts 26					4,830,000	4	47,291,274		4
ock, e of s					19,762		186,356		
					86		460		
l on							754,771		
sive								(3,855)	
								(24,027,016)	(2

31,								
$	$	10,695,108	$ 11	$ 125,566,705	$ (89,415,563)	$ (3,855)	$	3

The accompanying notes form an integral part of these consolidated and combined financial statements

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AQUINOX PHARMACEUTICALS, INC.

Notes to the consolidated and combined financial statements

(Expressed in U.S. dollars)

1. Nature of operations

Aquinox Pharmaceuticals, Inc. and its wholly owned subsidiary, Aquinox Pharmaceuticals (Canada) Inc., (consolidated and combined the Company see Note 2 Basis of presentation) is a clinical stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. Our primary focus is anti-inflammatory product candidates targeting SHIP1, which is a key regulator of an important cellular signaling pathway in immune cells, known as the PI3K pathway. Aquinox Pharmaceuticals (USA) Inc. was incorporated on May 31, 2007 in the State of Delaware, United States. On January 27, 2014, Aquinox Pharmaceuticals (USA) Inc. changed its name to Aquinox Pharmaceuticals, Inc. (Aquinox USA).

Aquinox Pharmaceuticals (Canada) Inc. (AQXP Canada), was originally incorporated under the name of 6175813 Canada Inc. on December 26, 2003 under the Canada Business Corporations Act. In May 2014, after a corporate restructuring, the name was changed to Aquinox Pharmaceuticals (Canada) Inc.

The Company operates in Vancouver, British Columbia, Canada.

2. Basis of presentation and summary of significant accounting policies

(a) Basis of presentation

The accompanying consolidated and combined financial statements are presented in United States (U.S.) dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Through a reorganization on March 12, 2014, AQXP Canada became a wholly owned subsidiary of Aquinox USA (see Note 3). Prior to the reorganization, management determined that AQXP Canada and Aquinox USA were entities under common control as each of AQXP Canada and Aquinox USA were owned beneficially by identical shareholders and as such the basis of presentation of financial results prior to March 12, 2014 was on a combined basis. Subsequent to March 12, 2014, the basis of presentation of the financial results is on a consolidated basis. All intercompany transactions have been eliminated.

(b) Capital requirements

The Company operates in a capital intensive business. To finance its operations, the Company is likely to require additional capital. The Company may seek to raise funds through equity or debt financing. There is no assurance that financing will be available to the Company or at terms acceptable to the Company. Failure to obtain sufficient funds on acceptable terms can have a negative impact on the Company s business, results of operations, financial condition, cash flows and future prospects.

(c) Foreign currency translation and transactions

The functional currency of the Company and its subsidiary is the U.S. dollar. Monetary assets and liabilities of the Company s operations denominated in a currency other than the U.S. dollar are re-measured into U.S. dollars at the exchange rate prevailing as at the balance sheet date. Non-monetary assets and liabilities are translated at historical exchange rates prevailing at each transaction date.

Income and expenses are re-measured at the average exchange rates prevailing during the period, with the exception of amortization which is translated at historical exchange rates. Exchange gains and losses on translation are included in the consolidated and combined statements of operations and comprehensive loss.

(d) Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant areas requiring management estimates include whether the use of the going concern assumption is appropriate, valuation of stock options and warrants, amortization and depreciation, accrual of expenses, valuation allowance for deferred income taxes, and contingencies. Actual results could differ from those estimates.

(e) Cash and cash equivalents

All highly liquid investments with maturities of three months or less at the date of acquisition are considered to be cash equivalents.

(f) Short and long term investments

Short-term investments consist of bank term deposits and U.S. government agency securities with initial maturities of less than a year. Long-term investments consist of U.S. treasury securities with initial maturities of greater than a year but less than two years. Short-term investments and long-term investments are both classified as available-for-sale and carried at their estimated fair value with unrealized gains and losses recorded as a component of other comprehensive income. Realized gains and losses are recorded in net loss. The Company periodically reviews its investments for impairment and when a decline in market value is deemed to be other than temporary, the loss is recognized in net loss.

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(g) Deferred offering costs

Deferred offering costs consist principally of professional fees incurred. These costs, together with the underwriter discount, were charged to gross proceeds of the initial public offering (IPO) upon completion of the offering on March 12, 2014.

(h) Property and equipment

Property and equipment are recorded at cost less accumulated amortization. Amortization of property and equipment has been provided using the straight-line basis over a range of five years, except for leasehold improvements which are amortized over the lesser of useful life and term of lease.

The Company reviews the carrying value of property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. In cases where undiscounted expected future cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of assets. The factors considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used, and the effects of obsolescence, demand, competition, and other economic factors. Based on management s assessment there was no impairment of property and equipment as at December 31, 2014 and 2013.

(i) Clinical trial accruals

As part of the process of preparing financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company s objective is to reflect the appropriate clinical trial expenses in the financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial.

During the course of a clinical trial, the Company adjusts the rate of clinical trial expense recognition if actual results differ from estimates. The Company prepares estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. Although the Company does not expect the estimates to be materially different from amounts actually incurred, the Company s understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. The Company s clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

(j) Taxes

The Company accounts for income taxes using ASC 740, Income Taxes which is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company s financial statements or tax returns. In estimating future tax consequences, ASC 740 generally considers all expected future events other than enactments of and changes in the tax law or rates. The measurement of deferred tax assets is reduced, if necessary, by the extent of the valuation allowance. ASC 740

clarifies the criteria that must be met prior to recognition of the financial statement benefit of a position taken in a tax return. ASC 740 provides a benefit recognition model with a two-step approach consisting of a more-likely-than-not recognition criteria, and a measurement attribute that measures a given tax position as the largest amount of tax benefits that are more than 50% likely of being realized upon ultimate settlement. ASC 740 also requires the recognition of liabilities created by differences between tax positions taken in a tax return and amounts recognized in the financial statements.

Investment tax credits relating to scientific research and experimental development are accounted for in operating expenses. To the extent there is reasonable assurance the credits will be realized, they are recorded in the period the related expenditure is made as an income tax (provision) recovery. If investment tax credit amounts subsequently received are less or more than originally recorded, the difference is treated as a change in estimate.

Canadian tax rules impose a tax with respect to Canadian corporation taxable preferred stock and their liquidation rights. In prior periods, AQXP Canada has recorded this tax on preferred stock as a non-current accrued tax payable on its balance sheet, on the same basis as it recorded the accretion of preferred stock.

(k) Redeemable convertible preferred stock

The Company classified redeemable convertible preferred stock that was redeemable outside of the Company s control as mezzanine equity. The Company recorded such redeemable convertible preferred stock at fair value upon issuance, net of any issuance costs or discounts. The carrying value of the redeemable convertible preferred stock was increased by periodic accretion to its redemption value.

In the absence of retained earnings, the accretion was recorded within additional paid-in capital to the extent there was a sufficient balance, rather than accumulated deficit. Only after exhausting the balance of accumulated paid-in capital, was the accretion recorded to accumulated deficit.

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(l) Research and development costs

Research and development costs are charged to expense as incurred and include items such as: employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies, the cost of acquiring, developing and manufacturing clinical trial materials, facilities, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, and other supplies and costs associated with clinical trials, preclinical activities, and regulatory operations.

Development costs are expensed in the period incurred unless management believes a development project meets generally accepted accounting criteria for deferral and amortization. No product development expenditures have been deferred to date. The Company records costs for certain development activities, such as clinical trials, based on management s evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated and combined financial statements as prepaid or accrued expense.

(m) Accounting for stock-based compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award will be recognized over the period during which services are provided in exchange for the award, generally the vesting period. All share-based payments to employees are recognized in the financial statements based upon their respective grant date fair values.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model. This approximation uses assumptions regarding a number of inputs that requires management to make significant estimates and judgments. Prior to the completion of the IPO in March 2014, the Company s common stock was not publicly traded. As a result, the expected volatility assumption is based on industry peer information. Additionally, because the Company has no significant history to calculate the expected term, the simplified method calculation was used.

(n) Segment reporting

The Company operates in one segment, the identification and development of therapeutics for inflammatory diseases and cancer. All of the Company s operations are performed in Canada. Total assets held in the U.S., comprised primarily of cash and cash equivalents, short-term investments and investments, were $31,099,142 as of December 31, 2014 (December 31, 2013 - $6,629,383).

(o) Net Loss per share

Basic net loss per common share is computed by dividing loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents, consisting of shares that might be issued upon exercise of common stock options and warrants. In periods where losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive.

(p) Derivative liabilities and fair value of financial instruments

The Company accounts for currently outstanding detachable warrants to purchase common stock as liabilities as they are freestanding derivative financial instruments. The warrants are recorded as liabilities at fair value, estimated using a Black-Scholes option pricing model, and marked to market at each balance sheet date, with changes in the fair value of the derivative liabilities recorded in the consolidated and combined statements of operations. The Company allocated the total consideration received for issuing preferred stock and warrants based on the relative fair value of each security at the date of issuance. This allocation resulted in a discount to the initial carrying amount of the preferred stock at the date of issuance amortized over the life of the preferred stock and was recorded as amortization of discount on preferred stock in the consolidated and combined statements of operations and comprehensive loss.

The Company also evaluates and accounts for conversion and redemption options embedded in convertible instruments as they can be free standing derivative financial instruments depending on certain criteria. If they are determined to be free standing derivative financial instruments, the Company records these as preferred stock embedded derivatives on its consolidated and combined balance sheets at fair value with changes in the fair values of these derivatives recorded in the consolidated and combined statements of operations and comprehensive loss.

The Company applies the residual value method to record the fair value of warrants issued with loans as a discount to the initial carrying amount of loans at the date of issuance. Loans are measured at amortized cost using the effective interest method which is a method of calculating the amortized cost of a financial liability and allocating the effective interest expense over the term of the financial liability. Interest expense is recorded in bank charges and financing costs in the consolidated and combined statements of operations and comprehensive loss. The interest rate is the rate that exactly discounts estimated future cash payments throughout the term of the financial instrument to the net carrying amount of the financial liability. Debt issuance costs are capitalized, recorded as deferred financing costs, and are amortized into financing costs in the consolidated and combined statements of operations and comprehensive loss using the effective interest method.

ASC 820, Fair Value Measurements requires disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances, and settlements relating to Level 3 measurements. It also clarifies existing fair value disclosures regarding the level of disaggregation and the inputs and valuation techniques used to measure fair value. ASC 820 defines fair value as the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The guidance also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

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

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

(q) Concentration of credit risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents, short-term investments and long-term investments. Cash, cash equivalents and investments are invested in accordance with the Company s investment policy. The primary objective for the Company s investment portfolio is the preservation of capital and maintenance of liquidity and includes guidelines on the quality of financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

(r) Recently issued and recently adopted accounting standards

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period in response to the EITF consensus on Issue 13-D. ASU 2014-12 clarifies that entities should treat performance targets that can be met after the requisite service period of a share-based payment award as performance conditions that affect vesting. Therefore, an entity would not record compensation expense (measured as of the grant date without taking into account the effect of the performance target) related to an award for which transfer to the employee is contingent on the entity s satisfaction of a performance target until it becomes probable that the performance target will be met. ASU 2014-12 is effective for all entities for reporting periods (including interim periods) beginning after December 15, 2015. Early adoption is permitted. The Company does not anticipate a material impact to the Company s financial position, results of operations or cash flows as a result of this change.

In June 2014, the FASB issued ASU 2014-10 Development Stage Entities, which resulted in the elimination of certain financial reporting requirements. The amendments remove all incremental financial reporting requirements from U.S. GAAP for development stage entities. The guidance removes the definition of a development stage entity and eliminates the requirements for development stage entities to: present inception-to-date amounts, label the financial statements as those of a development stage entity, disclose a description of the development stage activities in which the entity is engaged, and disclose the first year in which the entity is no longer a development stage entity. ASU 2014-10 is effective for annual reporting periods beginning after December 15, 2014, with early adoption permitted. On June 30, 2014, the Company elected to early adopt the provisions of ASU 2014-10. The adoption changed the presentation of certain financial statements and financial statement information, but did not have any other impact on the Company s financial statements. We have provided additional disclosures under (r) Risks and uncertainties as required by this ASU.

In August 2014, the FASB issued ASU 2014-15 Presentation of Financial Statements Going Concern, outlining management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern, along with the required disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016 with early adoption permitted. The Company does not anticipate a material impact to the Company s financial statements as a result of this change.

(s) Risks and uncertainties

The Company is subject to numerous risks and uncertainties. These risks, among others, included the following:

the Company has no source of revenue, has an accumulated deficit of $89,415,563 as of December 31, 2014, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as it continues development of, seeks regulatory approvals for, and potentially begins to commercialize AQX-1125, its lead product candidate, and any future product candidates;

the Company is likely to require additional capital to finance its operations which may not be available to it on acceptable terms, or at all;

the Company s success is primarily dependent on the regulatory approval and commercialization of AQX-1125, its lead product candidate, and any future product candidates;

SHIP1 has not been validated as a target;

the Company is subject to regulatory approval processes that are lengthy, time consuming and inherently unpredictable; the Company may not be able to obtain approval for AQX-1125 or any future product candidates from the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities;

the Company s intellectual property rights can be difficult and costly to protect;

the Company may not be able to recruit or retain key employees, including its senior management team;

the Company depends on the performance of third parties, including contract research organizations and third-party manufacturers; and

the Company faces competition from other pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others.

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3. Redeemable convertible preferred stock and stockholders (deficit) equity

On February 27, 2014, the Company effected a 1-for-19.2 reverse stock split of Aquinox USA s common stock and convertible preferred stock and AQXP Canada s common exchangeable shares and exchangeable preferred shares. All per share amounts and numbers of shares within the consolidated and combined financial statements and notes are presented on a post-split basis.

On March 12, 2014, immediately prior to the closing of the IPO, the Company underwent a reorganization, which resulted in a simplification of its capital structure. Each of the 301,745 outstanding common exchangeable shares of AQXP Canada was transferred to Aquinox USA in exchange for one share of common stock of Aquinox USA. Each of the 791,016 outstanding Series A exchangeable preferred shares, 793,617 outstanding Series B exchangeable preferred shares and 378,786 outstanding Series C exchangeable preferred share of AQXP Canada was transferred to Aquinox USA in exchange for one share of Series A, B and C convertible preferred stock of Aquinox USA, respectively. As a result, following such exchange, there were 1,453,891 shares of Series A, 2,367,414 shares of Series B and 1,722,210 shares of Series C convertible preferred stock of Aquinox USA. Following the completion of the exchange and conversion, all special voting shares of AQXP Canada and all special voting stock of Aquinox USA were redeemed for a nominal amount and all exchangeable preferred shares of AQXP Canada, now held by Aquinox USA, were converted to common exchangeable shares of AQXP Canada. As a result of the reorganization, AQXP Canada became a 100% owned subsidiary of Aquinox USA. Subsequent to this reorganization, all 5,543,515 of the outstanding shares of redeemable convertible preferred stock of Aquinox USA converted to an equivalent number of shares of common stock of Aquinox USA. The exchange and conversion resulted in the derecognition of non-cash accrued tax payable of $1,797,412 and the derecognition of the derivative liability for the redemption option on preferred stock of $800,206.

On March 12, 2014, the Company closed its IPO whereby the Company sold 4,830,000 shares of common stock (inclusive of 630,000 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of $11.00 per share before underwriting discounts. The shares began trading on the NASDAQ Global Market on March 7, 2014, under the symbol AQXP . The aggregate net proceeds received by the Company from the offering, net of underwriting discounts and commissions and offering costs of $5,838,726, were $47,291,274.

On March 12, 2014, the Company adopted an amended and restated certificate of incorporation for Aquinox USA, which authorized two classes of stock, common and preferred. The total number of shares Aquinox USA is authorized to issue is 55,000,000 shares, comprised of 50,000,000 common stock and 5,000,000 of a new category of preferred stock both with a par value of $0.000001 per share. As of December 31, 2014 and December 31, 2013, no shares of this new category of preferred stock were issued or outstanding.

4. Cash and cash equivalents

	DECEMBER 31, 2014	DECEMBER 31, 2013
Cash	$ 8,350,885	$ 7,292,116
Cash equivalents	6,555,202	3,714,276
	$ 14,906,087	$ 11,006,392

5. Accounts and other amounts receivable

	DECEMBER 31, 2014	DECEMBER 31, 2013
Refundable goods and services tax	$ 51,748	$ 22,494
Other	13,699	5,452
	$ 65,447	$ 27,946

6. Property and equipment

	DECEMBER 31, 2014		
	COST	ACCUMULATED AMORTIZATION	NET BOOK VALUE
Laboratory equipment	$	$	$
Leasehold improvements	142,740	109,988	32,752
Office computers and operating systems	165,364	95,495	69,869
Office furniture and equipment	74,457	72,384	2,073
	$ 382,561	$ 277,867	$ 104,694

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	DECEMBER 31, 2013		
	COST	ACCUMULATED AMORTIZATION	NET BOOK VALUE
Laboratory equipment	$ 59,523	$ 48,302	$ 11,221
Leasehold improvements	94,217	64,295	29,922
Office computers and operating systems	99,997	73,183	26,814
Office furniture and equipment	74,457	66,949	7,508
	$ 328,194	$ 252,729	$ 75,465

7. Accounts payable and accrued liabilities

	DECEMBER 31, 2014	DECEMBER 31, 2013
Trade accounts payable	$ 734,192	$ 599,833
Accrued clinical trial fees	3,751,872	565,170
Accrued compensation and vacation	382,254	247,667
Accrued professional fees	247,471	890,248
Other accruals	87,519	47,742
	$ 5,203,308	$ 2,350,660

8. Loan facility

On October 23, 2013, AQXP Canada entered into a term loan facility with Silicon Valley Bank (SVB) for up to $4 million, of which $2.5 million was received on October 30, 2013. In addition to principal, interest and other related payments due to SVB, Aquinox USA and AQXP Canada issued SVB warrants at $10.56 per warrant to purchase 11,363 shares of Series C preferred stock and a corresponding number of Canadian special voting shares of AQXP Canada. Following the completion of the IPO, the warrants are exercisable for 11,363 shares of common stock. These warrants expire in 2023.

On March 28, 2014, AQXP Canada made a cash payment of $2,609,844 to fully repay the amount outstanding under the term loan facility. The repayment was accounted for as an extinguishment of debt and the loss on extinguishment of $213,511 along with the prepayment penalty, repayment fee and accrued interest were recorded within bank charges and financing costs.

	AMOUNT
BALANCE - January 1, 2013	$
Bank loan cash received - October 30, 2013	2,500,000
Warrant discount	(226,255)
Financing costs	12,744
BALANCE - December 31, 2013	2,286,489

Accrued interest	9,844
Accretion of warrant discount	213,511
Repayment fee and penalty	100,000
Repayment of bank loan and interest	(2,609,844)
BALANCE - December 31, 2014	$

	DECEMBER 31, 2014	DECEMBER 31, 2013
Short-term portion of bank loan	$	$ 250,000
Long-term portion of bank loan		2,036,489
	$	$ 2,286,489

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9. Preferred stock

(a) Authorized

On March 12, 2014, the Company adopted an amended and restated certificate of incorporation for Aquinox USA. Aquinox USA is authorized to issue 5,000,000 of a new category of preferred stock with a par value of $0.000001 per share. As of December 31, 2014 and December 31, 2013, no shares of this new category of preferred stock were issued or outstanding.

Aquinox USA was authorized to issue the following preferred stock as of December 31, 2014 and December 31, 2013 with $0.000001 par value as follows:

TYPE	DECEMBER 31, 2014 NUMBER	DECEMBER 31, 2013 NUMBER
Preferred stock new	5,000,000	None
Series A preferred stock	None	27,914,951
Series B preferred stock	None	45,454,535
Series C preferred stock	None	45,793,738

AQXP Canada is authorized to issue the following preferred stock as of December 31, 2014 and December 31, 2013 with no par values as follows:

TYPE	DECEMBER 31, 2014 NUMBER	DECEMBER 31, 2013 NUMBER
Series A exchangeable preferred stock	Unlimited	Unlimited
Series B exchangeable preferred stock	Unlimited	Unlimited
Series C exchangeable preferred stock	Unlimited	Unlimited
Non-voting preferred stock	Unlimited	Unlimited

The Series A, B, and C preferred stock had the following attributes:

(i) Dividends: Preferred stock will receive a dividend simultaneously to common stockholders on an as-converted to common stock basis. These are non-cumulative and at the discretion of directors.

(ii) Voting rights: Series preferred and common stockholders vote together as a single class on an as-converted to common stock basis.

(iii) Liquidation preference: The Series C preferred stock is senior to Series A and Series B preferred stock with respect to dividend and redemption rights. In voluntary or involuntary liquidation, dissolution, change of control or winding up of the Company, the Series C preferred stockholders will receive two times the

original issue price of the preferred stock, plus 8% per annum of the original issue price compounded annually, and all declared but unpaid dividends on preferred stock. After payment of the Series C preference, the Series A and Series B stockholders will receive the original issue price per share of such series of preferred stock, plus 8% per annum of the original issue price compounded annually, and all declared but unpaid dividends on preferred stock. Assets and funds are then distributed pro rata to preferred stockholders and common stockholders until the holders of preferred stock have received total payments equal to three times the applicable original issue price. Any remaining assets and funds are distributed to the common stockholders.

(iv) Conversion options:

a. Optional Conversion: Preferred stock are convertible at any time at the option of the holder at a per share conversion price of $10.56 per share; or

b. Automatic Conversion: automatic conversion occurs in the event of (1) a qualified IPO; or (2) upon preferred stockholder approval.

(v) Redemption options:

a. Optional redemption: Preferred stock can be redeemed at the written request of holders of at least 65% of the preferred stock and preferred special voting stock at the liquidation preference as defined above. Redemption must be at least 5 years after the closing date of each Series. Upon any subsequent issuance of Series A, B, or C the redemption date of all issued series is automatically reset to 5 years from the latest issuance date. If shares subject to redemption are not redeemed due to funds being unavailable, these continue to be outstanding and entitled to all dividends, liquidation, conversion, and other preferences of series preferred shares until converted or redeemed; and

b. Mandatory redemption: Preferred stock shall be redeemed in the case of a liquidating event such as voluntary or involuntary liquidation, dissolution, or sale of the Company.

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Following the completion of the exchange and conversion, described in Note 3, all special voting shares of AQXP Canada and all special voting stock of Aquinox USA were redeemed for a nominal amount and all exchangeable preferred shares of AQXP Canada, now held by Aquinox USA, were converted to common exchangeable shares of AQXP Canada. Subsequent to this reorganization, all 5,543,515 of the outstanding shares of redeemable convertible preferred stock of Aquinox USA converted to an equivalent number of shares of common stock of Aquinox USA.

(b) Issuances of Series C preferred stock

On March 19, 2013, AQXP Canada issued 378,786 shares of Series C preferred stock at $10.56 per share for total consideration of $3,999,986 before issue costs of $49,758. In addition to the Series C preferred stock, in 2013 Aquinox USA also issued 378,786 shares of Series C Aquinox USA special voting stock, and AQXP Canada also issued 378,786 shares of Series C AQXP Canada special voting shares. Upon issuance of Series C the redemption date of Series A and B was reset to March 19, 2018.

On March 19, 2013, Aquinox USA issued 1,325,753 shares of Series C preferred stock at $10.56 per share for total consideration of $13,999,975 before issue costs of $174,153. In addition to the Series C preferred stock, in 2013 AQXP Canada also issued 1,325,753 shares of Series C AQXP Canada special voting shares. Upon issuance of Series C the redemption date of Series A and B was reset to March 19, 2018. Concurrent with the issuance of Series C preferred stock in March 2013, Aquinox USA also issued 17,671 warrants to holders of the Series C preferred stock. On December 23, 2013, the holders of the 17,671 warrants exercised their warrants into 17,671 shares of Series C preferred stock and equal number of Series C AQXP Canada special voting common shares (Note 10).

(c) Accounting for Series A, B and C preferred stock

The Series A, Series B and Series C preferred stock and Series A, Series B and Series C exchangeable preferred shares, collectively, the preferred stock are redeemable convertible preferred stock which were convertible into the Company s common stock and were classified as mezzanine equity for accounting purposes as they were redeemable on contingent events, and were redeemable at the option of the holder. The preferred stock were labeled within the convertible preferred stock and stockholders deficit as AQXP Canada exchangeable preferred shares, and Aquinox USA preferred stock.

Management evaluated the Series A and Series B preferred stock agreements and determined that there were no embedded conversion features and redemption options that were required to be bifurcated and accounted for separately as derivative financial instruments in the consolidated and combined financial statements. The Company recorded the Series A, Series B and Series C preferred stock at fair value upon issuance, with their carrying value increased by periodic accretion to their redemption value. The accretion was calculated using the liquidation preference of 8% per annum of the original issue price compounded annually over the period through the respective redemption dates.

Concurrent with the issuance of Series C preferred stock in March 2013, the Company also amended their respective certificates of incorporation, revising the terms, rights, and liquidation preferences for Series A and B preferred stock which required the Company to re-assess its previous embedded derivative analyses with respect to previous preferred stock offerings.

As a result the Company bifurcated the embedded mandatory redemption option based on contingent events in Series A, Series B and Series C preferred stock as it was determined the redemption option was no longer clearly and closely related to preferred stock host contract on March 19, 2013. The Company recorded the fair value of the embedded redemption options for Series A, Series B and Series C as derivative liabilities with changes in fair value of the

liabilities reflected in the consolidated and combined statements of operations and comprehensive loss as changes in fair value of derivative liabilities.

The table below discloses the accounting values assigned to the Series A, Series B and Series C preferred stock for the years ended December 31, 2014, 2013 and 2012. The Company recorded the Series A, Series B and Series C redeemable convertible stock at fair value upon issuance, with their carrying value increased by periodic accretion to their redemption value.

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	SERIES A PREFERRED STOCK			
	AQXP CANADA EXCHANGEABLE PREFERRED SHARES		AQUINOX USA PREFERRED STOCK	
	NUMBER	AMOUNT	NUMBER	AMOUNT
BALANCE December 31, 2011	791,016	$ 11,365,295	662,875	$ 9,503,860
Accretion for liquidation preference on preferred stock		915,252		769,236
Accretion for share issuance costs on preferred stock		39,751		34,936
BALANCE December 31, 2012	791,016	12,320,298	662,875	10,308,032
Accretion for liquidation preference on preferred stock		988,473		830,772
Accretion for share issuance costs on preferred stock		20,868		18,334
BALANCE December 31, 2013	791,016	13,329,639	662,875	11,157,138
Accretion for liquidation preference on preferred stock		190,112		159,782
Accretion for share issuance costs on preferred stock		75,007		49,783
Conversion of preferred stock into Aquinox USA common stock	(791,016)	(13,594,758)	(662,875)	(11,366,703)
BALANCE December 31, 2014		$		$

	SERIES B PREFERRED STOCK			
	AQXP CANADA EXCHANGEABLE PREFERRED SHARES		AQUINOX USA PREFERRED STOCK	
	NUMBER	AMOUNT	NUMBER	AMOUNT
BALANCE December 31, 2011	793,617	$ 9,076,826	1,573,797	$ 17,954,965
Accretion for liquidation preference on preferred stock		732,180		1,443,472
Accretion for share issuance costs on preferred stock		32,545		61,470
Amortization of warrant discount		21,883		23,567
BALANCE December 31, 2012	793,617	9,863,434	1,573,797	19,483,474
Accretion for liquidation preference on preferred stock		781,300		1,550,916
Accretion for share issuance costs on preferred stock		17,534		33,255
Amortization of warrant discount		21,825		23,505

BALANCE December 31, 2013	793,617	10,684,093	1,573,797	21,091,150
Accretion for liquidation preference on preferred stock		153,664		298,285
Accretion for share issuance costs on preferred stock		44,213		98,941
Amortization of warrant discount		27,144		85,030
Conversion of preferred stock into Aquinox USA common stock	(793,617)	(10,909,114)	(1,573,797)	(21,573,406)
BALANCE December 31, 2014		$		$

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	SERIES C PREFERRED STOCK			
	AQXP CANADA EXCHANGEABLE PREFERRED SHARES		AQUINOX USA PREFERRED STOCK	
	NUMBER	AMOUNT	NUMBER	AMOUNT
BALANCE December 31, 2012		$		$
Issuance of preferred stock, net of issuance costs of $49,758 for AQXP Canada and $174,153 for Aquinox USA	378,786	3,950,228	1,325,753	13,825,822
Warrant discount of $68,920 for Aquinox USA (Note 10)				(68,920)
Redemption discount of $466,673 for AQXP Canada and $1,633,357 for Aquinox USA		(466,673)		(1,633,357)
Accretion for liquidation preference on preferred stock		266,665		933,333
Accretion for share issuance costs on preferred stock		7,352		25,731
Amortization of warrant discount to date warrants exercised (Note 10)				10,838
Amortization of redemption option discount		73,389		256,863
Issuance of preferred stock on exercise of warrants (Note 10)			17,671	415,431
BALANCE December 31, 2013	378,786	3,830,961	1,343,424	13,765,741
Accretion for liquidation preference on preferred stock		60,785		273,534
Accretion for share issuance costs on preferred stock		41,896		148,932
Amortization of redemption option discount		393,283		1,378,776
Conversion of preferred stock into Aquinox USA common stock	(378,786)	(4,326,925)	(1,343,424)	(15,566,983)
BALANCE December 31, 2014		$		$

10. Warrants

Warrants issued with the Series C preferred stock (Note 9):

	NUMBER	AMOUNT
BALANCE December 31, 2012		$
Issued March 19, 2013	17,671	68,920
Change in fair value of derivative liability		343,118

Exercised	December 23, 2013	(17,671)	(412,038)
BALANCE	December 31, 2013		$
BALANCE	December 31, 2014		$

In March 2013, the Company issued 17,671 preferred stock purchase warrants in their Series C financing, exercisable at $0.19 per warrant. These warrants were exercised on December 23, 2013. The cash proceeds received of $3,393 and the fair value of the warrants at date of exercise of $412,038, totaling $415,431 in aggregate, was recorded as the carrying value of the Aquinox USA Series C preferred stock issued upon exercise of the warrants.

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Warrants issued with the bank loan (Note 8):

	NUMBER	AMOUNT
BALANCE December 31, 2012		$
Issued October 23, 2013	11,363	226,255
Change in fair value of derivative liability		(4,935)
BALANCE December 31, 2013	11,363	221,320
Change in fair value of derivative liability		(148,979)
BALANCE December 31, 2014	11,363	$ 72,341

The fair value of warrants on December 31, 2014 was estimated using the Black-Scholes pricing model with the following assumptions: (i) Expected volatility 100%; (ii) Expected term (years) 8.81 years; (iii) Risk free rate 2%

11. Common stock

(a) Authorized

Aquinox USA is authorized to issue 50,000,000 shares of common stock with a par value of $0.000001 per share (December 31, 2013 139,266,037).

As of December 31, 2014, total number of shares of common stock issued and outstanding was 10,695,108 (December 31, 2013 301,745).

(b) Stock option plan

On January 27, 2014, the stockholders of Aquinox USA approved a 2014 Equity Incentive Plan (2014 Plan). The 2014 Plan became effective on the date of the prospectus for the IPO, March 6, 2014. The 2014 Plan is the successor to and continuation of the Joint Canadian Stock Option Plan (the 2006 Plan). After the 2014 Plan became effective, no further grants will be made under the 2006 Plan. The 2014 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards, and other forms of equity awards to employees, directors, and consultants.

As of December 31, 2014, the maximum number of shares of common stock that may be issued under the 2014 Plan was 1,423,416, which number includes a number of shares of common stock equal to (i) 756,279 new shares, plus (ii) 70,310, the number of shares reserved for issuance under the 2006 Plan at the time the 2014 Plan became effective, plus (iii) any shares subject to stock options or other stock awards granted under the 2006 Plan that would have otherwise returned to the 2006 Plan, such as upon the expiration or termination of a stock award prior to vesting. Additionally, the number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year for a period of up to 10 years, beginning on January 1, 2015 and ending on and including January 1, 2024, by 4% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors.

At December 31, 2014, the number of options available to be granted was 598,812 (December 31, 2013 736,333).

Stock option transactions and the number of stock options outstanding are summarized below:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	AGGREGATE INTRINSIC VALUE
Outstanding at December 31, 2013	628,754	$ 8.83	7.50	
Options granted	229,082	10.13		
Options exercised	(86)	5.76		
Options forfeited/expired	(33,146)	5.98		
Outstanding at December 31, 2014	824,604	$ 6.79	7.16	$ 788,840
Exercisable as of December 31, 2014	429,369	$ 6.79	5.58	$ 646,363

During the year ended December 31, 2014, the Company granted 195,750 stock options to employees and 33,332 stock options to directors. The stock options granted to employees have exercise price per share ranging from $6.73 to $10.10 and vest 25% one year after the beginning of the vesting period and thereafter ratably each month over the following thirty-six months. The stock options granted to directors have exercise price per share of $11.00 and vest over three years at equal annual installment from the beginning of the vesting period. All stock options under the 2014 Plan are subject to a 10 year expiration period.

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During the year ended December 31, 2014, 86 shares of common stock were issued upon exercise of options with an aggregate intrinsic value of $141.

(c) Stock-based compensation

The fair value of stock options granted is estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	DECEMBER 31, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Expected volatility	108%	94%	90%
Expected dividends	0%	0%	0%
Expected terms (years)	6.00	6.25	6.25
Risk free rate	1.67%	2.11%	1.79%
Weighted average grant-date fair value of stock options	$ 8.19	$ 0.40	$ 0.14

Stock options are granted with exercise prices as determined by the Board of Directors at the date of grant. The expected term represents the period that the Company s stock-based awards are expected to be outstanding. As prior to the completion of the IPO in March 2014, the Company was a private company, the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted. The Company has based its expected term for awards issued to employees on the simplified method, which represents the average period from vesting to the expiration of the stock option. In addition, the Company does not have sufficient trading history for the Company s common stock, and therefore, the expected stock price volatility for the Company s common stock was estimated by taking the average historical price volatility for industry peers. The Company has never declared or paid any cash dividends to common stockholders and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero. The risk-free interest rate was based on the yields of treasury securities with maturities similar to the expected term of the options for each option group.

The Company amortizes the fair value of the stock options on a straight-line basis over the applicable requisite service periods of the awards, which is generally the vesting period. The weighted average grant date fair values of stock options granted for the years ended December 31, 2014, 2013 and 2012 were $8.19, $0.40 and $0.14, respectively. Stock-based compensation expense charged to income for the plans was $854,188, $349,321 and $351,322 for the years ended December 31, 2014, 2013 and 2012, respectively. Total unrecognized compensation cost for all stock-based compensation plans was $2,643,323 as of December 31, 2014, which is expected to be recognized over a weighted-average period of 2.94 years.

12. Net loss per share

In connection with the IPO, the Company s capital structure was reorganized such that AQXP Canada became a wholly owned subsidiary of Aquinox USA, and the holders of the preferred shares of AQXP Canada and common shares of AQXP Canada exchanged their shares for shares of preferred stock or common stock, respectively, of Aquinox USA (see Note 3). In addition, the holders of preferred shares of Aquinox USA converted their shares into shares of common stock of Aquinox USA. In connection with the IPO, the Company effected a 1-for-19.2 reverse stock split. The common stock, options and warrants outstanding as of the completion of the reorganization were 5,845,260 shares, 628,754 options and 11,363 warrants, respectively. Basic and diluted earnings per share has been retroactively restated for all periods prior to the reorganization.

Basic and diluted net loss per common share are presented using the two-class method required for participating securities. If a dividend is paid on common stock, the holders of preferred stock are entitled to a proportionate share of any such dividend as if they were holders of common stock (on an if-converted basis). The Company considers its preferred stock to be participating securities and, in accordance with the two-class method, earnings allocated to participating securities and the related number of outstanding shares of participating securities have been excluded from the computation of basic and diluted net loss per common share.

The Company considers the Aquinox USA common stock to be their participating stock that is subordinate to all other stock or shares of the Company. These shares are used by the Company when computing its loss per share. Under the two-class method, net loss attributable to common stockholders is determined by allocating undistributed loss between common stock and participating securities. Undistributed loss is calculated as net loss less distributed loss, accretion of liquidation preference on preferred stock, accretion of share issuance costs on preferred stock, and tax expense on preferred stock. As holders of preferred stock, holders of stock options and holders of common stock warrants do not have contractual obligations to share in the losses of the Company, the net loss attributable to common stockholders for each period is not allocated between common stock and participating securities. Accordingly, outstanding stock options, common stock warrants and preferred stock are excluded from the calculation of basic and diluted net loss per share as the effect would have been anti-dilutive.

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The detail of the computation of basic and diluted earnings per share is as follows:

	DECEMBER 31, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Numerator			
Net loss	$ (24,027,016)	$ (8,729,371)	$ (7,714,198)
Accretion for liquidation preference on preferred stock	(1,132,893)	(5,351,459)	(3,860,140)
Accretion for share issuance costs on preferred stock	(19,551)	(123,074)	(168,702)
Tax expense on preferred stock	(100,291)	(737,925)	(394,908)
Reversal of tax payable on preferred stock due to conversion of preferred stock	1,897,702		
Extinguishment of remaining share issuance costs due to conversion of preferred stock	(439,227)		
Total loss attributable to common stockholders	$ (23,821,276)	$ (14,941,829)	$ (12,137,948)
Denominator			
Weighted average shares used to compute basic and diluted net loss per common share	8,667,387	301,745	301,745
Net loss per share attributable to common stockholders basic and diluted	$ (2.75)	$ (49.52)	$ (40.23)

The following have been excluded from the computation of basic and diluted net loss per share as their effect would have been antidilutive:

	DECEMBER 31, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Convertible preferred stock		5,543,515	3,821,305
Outstanding stock options	824,608	628,754	551,584
Common stock warrants	11,363	11,363	
Total	835,971	6,183,632	4,372,889

13. Income taxes

Income tax expense (recovery) varies from the amounts that would be computed by applying the expected Canadian income tax rate (26%) and U.S. income tax rates (35%). The combined Canadian and U.S. income tax rates of 27.3% (2013 25.6%; 2012 25.1%) was applied to loss before income taxes as shown in the following table:

	DECEMBER 31, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Computed taxes at combined Canadian and U.S. tax rates	$ (6,561,056)	$ (2,235,488)	$ (1,936,264)
Change in Canadian tax rate		(363,706)	
Non-deductible expenses	185,041	93,663	119,829
Investment tax credits[(i)]	(222)	(5,044)	42,294
Change in valuation allowance	4,519,695	2,500,412	1,719,347
Reversal of tax benefit related to taxable preferred stock	1,684,713		
Other impact upon conversion of taxable preferred stock	171,607	5,119	97,088
Income tax (recovery) expense [(i)]	$ (222)	$ (5,044)	$ 42,294

(i) Income tax (recovery) expense for the years ended December 31, 2014, 2013 and 2012 were all related to AQXP Canada s Canadian investment tax credits. For periods prior to June 2010, AQXP Canada was able to claim Canadian refundable investment tax credits. As described in Note 2(i), when investment tax credits subsequently received are less or more than originally recorded, the difference is treated as a change in estimate and recorded as part of current income tax expense (recovery); in 2012 claims received were less than originally recorded and accordingly AQXP Canada recognized an income tax expense for this difference.

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	DECEMBER 31, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Net (loss) income before taxes:			
Canada	$ (20,538,640)	$ (8,881,697)	$ (7,431,876)
U.S.	(3,488,598)	147,282	(240,028)
Total	$ (24,027,238)	$ (8,734,415)	$ (7,671,904)

Deferred income tax assets and liabilities result from the temporary differences between the amount of assets and liabilities recognized for financial statement and income tax purposes. The significant components of the deferred income tax assets are as follows:

	DECEMBER 31, 2014	DECEMBER 31, 2013
Canadian net operating losses	$ 13,858,491	$ 10,560,895
U.S. net operating losses	1,403,318	477,682
Research and development deductions and credits	4,947,218	4,933,498
Other	404,810	122,066
Less: valuation allowance	(20,613,837)	(16,094,141)
Net deferred income tax assets	$	$

At December 31, 2014, the Company had net Canadian operating losses carried forward for tax purposes which were available to reduce taxable income of future years of approximately $53,302,000 (December 31, 2013 approximately $34,139,000) expiring commencing in 2026 through 2034, and net US operating losses carried forward for tax purposes which were available to reduce taxable income of future years of approximately $4,009,000 (December 31, 2013 approximately $1,365,000).

The Company also had unclaimed Canadian tax deductions with no expiry for scientific research and experimental development expenditures of approximately $10,532,000 at December 31, 2014 (December 31, 2013 approximately $10,535,000). In addition, at December 31, 2014, the Company had approximately $2,698,000 (December 31, 2013 approximately $2,700,000) of investment tax credits available to offset Canadian federal and provincial taxes payable expiring commencing in 2027 through 2034.

Prior to the reorganization on March 12, 2014, the Company accrued non-current tax payable with respect to Canadian tax rules which impose a tax on Canadian corporation taxable preferred shares and their liquidation rights (Note 9). Upon the stock converting into common shares at the time of the reorganization (Note 3), the accrued tax payable amount was derecognized in the financial statements. At December 31, 2014, the Company had accrued a non-current tax payable on preferred stock of $0 (December 31, 2013 $1,797,412).

Under ASC 740, the benefit of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of the benefit of an uncertain tax position may be recognized if the position has less than a 50% likelihood of being sustained. The Company currently does not have any unrecognized tax benefits of uncertain tax positions. The Company does not expect any significant increases to its unrecognized tax benefits within twelve months of the

reporting date.

The Company currently files income tax returns in the United States and Canada, the jurisdictions in which the Company believes that it is subject to tax. Further, while the statute of limitations in each jurisdiction where an income tax return has been filed generally limits the examination period, as a result of loss carry-forwards, the limitation period for examination generally does not expire until several years after the loss carry-forwards are utilized. Other than routine audits by tax authorities for tax credits and tax refunds that the Company has claimed, management is not aware of any other material income tax examination currently in progress by any taxing jurisdiction.

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14. Financial instruments

Securities classified as available for sale

The Company s short-term investments and long-term investments are consisted of available-for-sale securities as follows:

December 31, 2014

Short-term investments:	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. treasury securities	$ 12,199,357	$	$ (5,438)	$ 12,193,919
U.S. Government agency securities	11,995,946	1,354		11,997,300
	$ 24,195,303	$ 1,354	$ (5,438)	$ 24,191,219
Long-term investments:				
U.S. Government agency securities	$ 2,002,870	$ 229	$	$ 2,003,099
Contractual maturities:				
Due within one year	$ 24,195,303			$ 24,191,219
Due after one year through two years	2,002,870			2,003,099

December 31, 2013

Short-term investments:	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Bank guaranteed investment certificate	$ 2,820,600	$	$	$ 2,820,600
Contractual maturities:				
Due within one year	$ 2,820,600			$ 2,820,600

The aggregate estimated fair value of the Company s investments with unrealized losses are as follows:

	Period of continuous unrealized loss			
	12 months or less		Greater than 12 months	
December 31, 2014	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses
U.S. treasury securities	$ 12,193,919	$ (5,438)	NA	NA
December 31, 2013	NA	NA	NA	NA

Fair value of financial instruments

The fair value of the Company s financial instruments are determined according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

The determination of a financial instrument s level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The carrying amounts of certain of the Company s financial instruments including cash, cash equivalents, accounts and other amounts receivable, accounts payable, and accrued liabilities, approximate their fair values because of their nature and/or short maturities. The Company holds short and long-term investments that are classified as available-for-sale securities, which are measured at fair value determined on a recurring basis according to the fair value hierarchy.

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The following tables present the fair value of our financial instruments that are measured at fair value on a recurring basis:

	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT UN-OBSERVABLE INPUTS (LEVEL 3)	TOTAL
BALANCES December 31, 2014				
Short-term investments U.S. treasury securities	$ 12,193,919	$	$	$ 12,193,919
Short-term investments U.S. government agency securities	11,997,300			11,997,300
Investments U.S. treasury securities				
Investments U.S. government agency securities	2,003,099			2,003,099
Bank loan warrant derivative liabilities			(72,341)	(72,341)
	$ 26,194,318	$	$ (72,341)	$ 26,121,977
BALANCES December 31, 2013				
Short-term investments bank term deposits	$	$ 2,820,600	$	$ 2,820,600
Bank loan warrant derivative liabilities			(221,320)	(221,320)
Redemption option on preferred stock			(800,206)	(800,206)
	$	$ 2,820,600	$ (1,021,526)	$ 1,799,074

Level 1 instruments, which include investments that are valued based on quoted market prices in active markets, consisted of U.S. Treasury and U.S. government agency securities.

Level 2 instruments, which include investments for which all significant inputs are observable, consisted of bank term deposits.

Level 3 instruments consisted of the Company s preferred stock embedded feature and warrants which are accounted for as derivative liabilities. The Company used Level 3 inputs for the valuation methodology of the derivative liabilities. The estimated fair values were computed using a Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these derivative liabilities including the fair value

per share of the underlying stock, remaining contractual term of the warrants and redeemable convertible preferred stock, risk-free interest rate, expected dividend yield, credit spread, and expected volatility of the underlying stock. The derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in change in fair value of derivative liabilities:

Fair value of significant unobservable inputs (Level 3):

	BANK LOAN WARRANT DERIVATIVE LIABILITIES	PREFERRED STOCK EMBEDDED DERIVATIVE LIABILITIES	TOTAL
BALANCES December 31, 2013	$ 221,320	$ 800,206	$ 1,021,526
Change in fair value of derivative liabilities	(148,979)		(148,979)
Derecognition of liabilities upon preferred stock conversion to common stock conversion		(800,206)	(800,206)
BALANCES December 31, 2014	$ 72,341	$	$ 72,341

There were no transfers between Levels 1, 2, and 3 during the years ended December 31, 2014 and December 31, 2013.

At December 31, 2014, the Company had short-term investments consisting of available for sale securities of $24,191,219 and long-term investments consisting of available for sale securities of $2,003,099. Total gains for securities were $20,803 as of December 31, 2014. The Company s long-term investments had contractual maturities of less than 24 months.

15. License and patent agreements

(a) SHIP1 product candidates

In June 2006, the Company entered into an exclusive license agreement with the University of British Columbia (UBC), which was subsequently amended with the latest amendment in April 2010. Pursuant to this agreement, UBC granted the Company a worldwide license to certain small molecule compounds and pharmaceutical compositions that are modulators of SHIP1 activity. The agreement expires at the earlier of the last expiry of any patent obtained related to the technology or through enactment of one of the termination clauses stipulated in the agreement.

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The terms of the agreement required the Company to pay an initial license fee of CAD $50,000 which was settled by the issuance of 100,000 common exchangeable shares of AQXP Canada as consideration. Under the terms of the agreement, UBC will be paid low single-digit royalties in respect to any future revenues on aggregate worldwide net sales of products covered by the licensed patents, a percentage of sublicensing revenue, reimbursement of patent costs incurred by UBC related to the technology, an annual maintenance fee, and contingent payments subject to achieving certain development milestones totaling up to CAD $2,200,000 for the first drug product and CAD $1,500,000 for each subsequent drug product paid in cash or shares. The Company paid annual maintenance fees of CAD $1,000 related to this agreement for the year ended December 31, 2014 (December 31, 2013 CAD $1,000). The Company does not currently have any product candidates under development that are covered by the UBC license agreement.

(b) SHIP1 enzyme and screening of product candidates

In May 2005, the Company entered into an assignment agreement, which was subsequently amended with the latest amendment in March 2006, with the British Columbia Cancer Agency (BCCA) and StemCell Technologies, Inc. (STI), for the assignment to the Company of the 2002 exclusive license agreement between BCCA and STI to certain patents relating to technology relating to SHIP1. Subsequent to the initial agreement, the license agreement between the Company and BCCA was amended and restated, with the latest amendment in February 2013. The revisions, among other items, included an amended schedule of the technology licensed under this agreement. BCCA has granted the Company an exclusive worldwide license to certain of its intellectual property relating to core SHIP1 technology, and screening of compounds for activity using SHIP1, including the C2 binding domain. The agreement is to expire at the later of 20 years from the effective date of the agreement or upon the expiration of the last patent covered by the license.

The terms of the assignment agreement, required the Company to pay an assignment license fee of CAD $150,000, paid in stages beginning May 2005 and ending March 2006. The Company does not currently have any product candidates under development that are covered by the BCCA license agreement, nor has the Company sublicensed its rights under the licensed patents. However, if the Company develops products covered by the BCCA technology in the future, the Company will be required to pay BCCA low single-digit royalties based on aggregate worldwide net sales of products covered by the licensed patents, and if the Company sublicenses any rights to the technology, the Company will be required to pay BCCA a low double digit percentage of sublicensing revenue. The Company is also required to reimburse BCCA s patent costs incurred in relation to the licensed technology, and pay an annual maintenance fee in the amount of CAD $5,000. The Company s license with BCCA will terminate automatically upon the Company s insolvency, and may be terminated by either party for material breach by the other party. The Company incurred maintenance fees of CAD $5,000 related to this agreement during the years ended December 31, 2014, 2013 and 2012.

(c) AQX-1125

In August 2009, the Company entered into an asset purchase agreement with Biolipox AB of Sweden for the purchase of certain assets, including patent rights relating exclusively or principally to a specific class of compounds, which include AQX-1125.

The terms of the agreement required the Company to pay CAD $50,000 immediately. Upon the first submission to the FDA of an Investigational New Drug (IND) for a compound from the acquired class of compounds, the Company was required to pay an additional CAD $250,000 in exchangeable shares. A further one-time CAD $3,000,000 milestone payment is payable within 30 days of the commitment of financial resources by the Boards of Directors to advance one of the compounds from the acquired class of compounds into a Phase 3 clinical trial. Certain other milestone payments, totaling CAD $1,500,000 are payable upon the first commercial sale following regulatory approval of the

first compound in each of the United States, Europe and Japan. The development of the technology is actively proceeding. There are no royalty payments due under this agreement as at December 31, 2014.

In June 2014, the Company issued 19,762 shares of common stock to Biolipox AB as payment for achievement of the milestone upon the first submission to the FDA of an IND for AQX-1125. The fair value of the shares issued to Biolipox was $186,356, which was charged to research and development expense. Fair value was determined based on the closing price of the Company s common stock on the NASDAQ Global Market on the date of the share issuance. There were no expenses incurred by AQXP Canada relating to this agreement during the years ended December 31, 2013 and 2012.

16. Commitments and contingencies

	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating lease obligations[1]	$ 217,296	$ 172,026	$ 45,270	$	$

1. AQXP Canada has a lease agreement for office space which commenced on January 1, 2014 and expires March 31, 2016. The dollar amounts shown in these columns reflect the US$ equivalent of the obligations. The amounts were converted to U.S. dollars from Canadian dollars using the average of the daily noon exchange rates for the year ended December 31, 2014. Applying this formula, Canadian $1.00 was equal to US$0.9054.

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In the ordinary course of business, the Company may be subject from time to time to various proceedings, lawsuits, disputes, or claims. Although the Company cannot predict with assurance the outcome of any litigation, they do not believe there are currently any such actions that, if resolved unfavorable, would have a material impact on the Company s financial condition, results of operations or cash flows.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures.
(a) *Evaluation of disclosure controls and procedures.* Our Chief Executive Officer and our Chief Financial Officer have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this annual report. Based on that evaluation, they have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were, in design and operation, effective.

(b) *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(c) *Management s Report on Internal Control Over Financial Reporting.* This Annual Report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Item 9B. Other Information.
None.

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PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2014 fiscal year pursuant to Regulation 14A for our 2015 Annual Meeting of Stockholders, or the 2015 Proxy Statement, and the information to be included in the 2015 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

(1) The information required by this Item concerning our executive officers and our directors and nominees for director, including information with respect to our audit committee and audit committee financial expert, may be found under the section entitled Proposal No. 1 Election of Directors Information Regarding the Board of Directors and Corporate Governance, Information Regarding Committees of the Board of Directors and Executive Officers appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning our code of ethics may be found under the section entitled Information Regarding the Board of Directors and Corporate Governance appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

(3) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item may be found under the sections entitled Director Compensation and Executive Compensation and Equity Compensation Plan Information appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

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

(1) The information required by this Item with respect to security ownership of certain beneficial owners and management may be found under the section entitled Security Ownership of Certain Beneficial Owners and Management appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item with respect to securities authorized for issuance under our equity compensation plans may be found under the sections entitled Equity Compensation Plan Information appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

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

(1) The information required by this Item concerning related party transactions may be found under the section entitled C Transactions with Related Persons appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning director independence may be found under the sections entitled Information Regarding the Board of Directors and Corporate Governance Independence of the Board of Directors and Information Regarding Committees of the Board of Directors appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item may be found under the section entitled Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm appearing in the 2015 Proxy Statement. Such information is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) Financial Statements and Report of Independent Registered Public Accounting Firm

(2) Financial Statement Schedules

Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits are incorporated herein by reference or are filed with this report as indicated below (numbered in accordance with Item 601 of Regulation S-K).

(b) Exhibits

The exhibits listed on the Exhibit Index (following the Signatures section of this report) are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

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SIGNATURES

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

Aquinox Pharmaceuticals, Inc.

Date: March 16, 2015 By: /s/ David J. Main

David J. Main

President & Chief Executive Officer

(Principal Executive Officer)

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

Signature	Title	Date
/s/ David J. Main David J. Main	Director, President & CEO (Principal Executive Officer)	March 16, 2015
/s/ Kamran Alam Kamran Alam	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2015
/s/ Gary Bridger Gary Bridger	Director	March 16, 2015
/s/ Daniel Levitt Daniel Levitt	Director	March 16, 2015
/s/ Sean Nolan Sean Nolan	Director	March 16, 2015
/s/ Robert Pelzer Robert Pelzer	Director	March 16, 2015
/s/ Todd Simpson Todd Simpson	Director	March 16, 2015

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EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Aquinox Pharmaceuticals, Inc.	8-K	001-36327	3.1	March 12, 2014	
3.2	Amended and Restated Bylaws of Aquinox Pharmaceuticals, Inc.	S-1	333-193615	3.6	February 28, 2014	
4.1	Specimen Common Stock Certificate of the Aquinox Pharmaceuticals, Inc.	10-Q	001-36327	4.1	May 13, 2014	
4.2	Amended and Restated Qualification and Registration Rights Agreement of the Registrant, dated March 19, 2013.	S-1	333-193615	4.1	January 28, 2014	
4.3	Warrant to Purchase Stock of the Registrant, issued to Silicon Valley Bank, dated October 23, 2013.	S-1	333-193615	4.7	January 28, 2014	
10.1+	Joint Canadian Stock Option Plan.	S-1	333-193615	10.1	January 28, 2014	
10.2+	Forms of Option Agreement for Registrant s Joint Canadian Stock Option Plan.	S-1	333-193615	10.2	January 28, 2014	
10.3+	2014 Equity Incentive Plan	S-1	333-193615	10.3	January 28, 2014	
10.4+	Forms of Option Agreement and Option Grant Notice for Registrant s 2014 Equity Incentive Plan	S-1	333-193615	10.4	January 28, 2014	
10.5+	Form of Executive Employment Agreement.	10-Q	001-36327	10.1	November 4, 2014	
10.6	Form of Indemnity Agreement entered into between the Registrant and each of its directors and its executive officers.	S-1	333-193615	10.5	January 28, 2014	
10.7	Asset Purchase Agreement by and between the Registrant and Biolipox AB, dated August 19, 2009.	S-1	333-193615	10.12	February 28, 2014	
10.8	Consent to Sublease dated December 11, 2013 between 560677 B.C. LTD. and Mark Anthony Group Inc. and Aquinox Pharmaceuticals Inc.	S-1	333-193615	10.16	February 28, 2014	
10.9		S-1	333-193615	10.11	January 28, 2014	

	Offer to Lease by and between the Registrant and Sun Life Assurance Company of Canada, dated February 15, 2010.					
10.10	Loan Agreement by and between Aquinox Pharmaceuticals Inc. and Silicon Valley Bank, dated October 23, 2013.	S-1	333-193615	10.13	January 28, 2014	
10.11	Security Agreement by and between the Registrant and Silicon Valley Bank, dated October 23, 2013.	S-1	333-193615	10.14	January 28, 2014	
10.12	Security Agreement by and between Aquinox Pharmaceuticals Inc. and Silicon Valley Bank, dated October 23, 2013.	S-1	333-193615	10.15	January 28, 2014	
21.1	List of subsidiaries of the Registrant.	S-1	333-193615	21.1	January 28, 2014	
23.1	Consent of Deloitte LLP, Independent Registered Public Accounting Firm.					X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.					X
32.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.					X
101.INS	Instance Document.					

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Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
101.SCH	XBRL Taxonomy Extension Schema Document.					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

+ Indicates a management contract or compensatory plan.
Pursuant to a request for confidential treatment, portions of this exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

* Document has been furnished, is not deemed filed and is not to be incorporated by reference into any of the Company s filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in any such filing.