AQUINOX PHARMACEUTICALS, INC
Form 10-Q
November 10, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a 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

As of November 9, 2015, there were 17,211,986 shares of the registrant s common stock outstanding.

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Aquinox Pharmaceuticals, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2015

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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. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

AQUINOX PHARMACEUTICALS, INC.

Condensed consolidated balance sheets

(Unaudited)

(In thousands of U.S. dollars, except share amounts)

	SEPTEMBER 30, 2015	DECEMBER 31, 2014
Assets		
Current assets		
Cash and cash equivalents (Note 3)	$ 109,373	$ 14,906
Short-term investments (Note 7)	8,038	24,191
Accounts and other amounts receivable	19	65
Prepayments and deposits	505	139
Total current assets	117,935	39,301
Property and equipment	81	105
Long-term investments (Note 7)		2,003
Other	12	13
Total assets	$ 118,028	$ 41,422
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$ 3,859	$ 5,203
Total current liabilities	3,859	5,203
Warrant liabilities (Note 7)	142	72
Total liabilities	$ 4,001	$ 5,275
Stockholders equity		
Share capital: (Note 5)		
Common stock - $0.000001 par value - authorized, 50,000,000 as of September 30, 2015 (December 31, 2014 50,000,000); issued and outstanding, 17,211,986 as of September 30, 2015 (December 31,	0	0

2014 10,695,108)				
Additional paid-in capital		219,637		125,567
Accumulated deficit		(105,613)		(89,416)
Accumulated other comprehensive income (loss)		3		(4)
Total stockholders equity		114,027		36,147
Total liabilities and stockholders equity	$	118,028	$	41,422

The accompanying notes form an integral part of these unaudited condensed consolidated financial statements

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AQUINOX PHARMACEUTICALS, INC.

Condensed consolidated statements of operations and comprehensive loss

(Unaudited)

(In thousands of U.S. dollars, except per share and share amounts)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014	2015	2014
Operating expenses				
Research and development	$ 3,687	$ 5,323	$ 11,873	$ 11,754
General and administrative	1,230	987	3,874	2,803
Total operating expenses	4,917	6,310	15,747	14,557
Other income (expenses)				
Bank charges and financing costs	(4)	(2)	(15)	(459)
Change in fair value of derivative liabilities (Note 7)	(76)	29	(70)	958
Amortization and extinguishment of remaining discount on preferred shares upon conversion of preferred shares				(1,884)
Other income (expenses)	(38)	(1)	(365)	5
	(118)	26	(450)	(1,380)
Net loss before income taxes	(5,035)	(6,284)	(16,197)	(15,937)
Net loss	$ (5,035)	$ (6,284)	$ (16,197)	$ (15,937)
Net loss per common stock - basic and diluted (Note 6)	$ (0.43)	$ (0.59)	$ (1.46)	$ (1.97)
Basic and diluted weighted average common stock outstanding (Note 6)	11,841,147	10,695,042	11,096,369	7,984,052
Comprehensive loss:				
Net loss	$ (5,035)	$ (6,284)	$ (16,197)	$ (15,937)
Other comprehensive (loss) income unrealized (loss)/gain on available for sale securities	(1)	6	7	7
Comprehensive loss	$ (5,036)	$ (6,278)	$ (16,190)	$ (15,930)

The accompanying notes form an integral part of these unaudited condensed consolidated financial statements

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AQUINOX PHARMACEUTICALS, INC.

Condensed consolidated statements of cash flows

(Unaudited)

(In thousands of U.S. dollars)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014
Operating activities		
Net loss	$ (16,197)	$ (15,937)
Non-cash items and reclassifications:		
Financing costs		320
Fees and penalty on bank loan repayment		100
Amortization and extinguishment of remaining discount on preferred stock upon conversion of preferred stock		1,884
Change in fair value of derivative liabilities	70	(958)
Stock-based compensation	1,145	585
Stock-based purchase of patent rights		186
Foreign exchange loss and others	39	218
Changes in operating assets and liabilities:		
Accounts and other amounts receivable	46	(48)
Prepayments and deposits	(364)	(125)
Accounts payable and accrued liabilities	(1,515)	2,983
Cash used in operating activities	(16,776)	(10,792)
Investing activities		
Purchase of investments		(36,474)
Proceeds from maturity of investments	18,163	6,920
Purchase of property and equipment	(16)	(86)
Sale of property and equipment		16
Cash (used in) provided by investing activities	18,147	(29,624)
Financing activities		
Bank loan repayment, fees and penalty		(2,600)
Proceeds from exercise of stock options	1,121	
Public offering of common shares	98,038	53,130
Public offering costs	(6,063)	(5,251)
Cash (used in) provided by financing activities	93,096	45,279

Increase (decrease) in cash and cash equivalents during the period	94,467	4,863
Cash and cash equivalents, beginning of period	14,906	11,006
Cash and cash equivalents, end of period	$ 109,373	$ 15,869
Supplemental disclosure of cash flow information:		
Interest paid	$	$ 32
Interest received	$ 36	$ 80
Non-cash financing activities:		
Accrued offering costs	$ 169	$ 50

The accompanying notes form an integral part of these unaudited condensed consolidated financial statements

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AQUINOX PHARMACEUTICALS, INC.

Notes to the condensed consolidated financial statements

(Unaudited)

(In thousands of U.S. dollars, except per share and share amounts)

1. Nature of operations

Aquinox Pharmaceuticals, Inc. and its wholly owned subsidiary, Aquinox Pharmaceuticals (Canada) Inc., (consolidated, the Company) is a clinical stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. The Company s primary focus is anti-inflammatory product candidates targeting SHIP1 (SH2-containing inositol-5 -phosphatase 1), which is a key regulator of an important cellular signaling pathway in immune cells, known as the PI3K pathway.

Aquinox Pharmaceuticals, Inc. was originally incorporated under the name of Aquinox Pharmaceuticals (USA) Inc. 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. Condensed summary of significant accounting policies

(a) Basis of presentation

The accompanying unaudited condensed consolidated 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) and pursuant to the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, these financial statements do not include all of the information and footnotes required for complete financial statements and should be read in conjunction with the audited consolidated and combined financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014. Unless indicated otherwise, all amounts herein are expressed in thousands of United States dollars.

In management s opinion, the unaudited condensed consolidated financial statements reflect all adjustments (including reclassifications and normal recurring adjustments) necessary to present fairly the financial position as of September 30, 2015, and results of operations and cash flows for all periods presented. The interim results presented are not necessarily indicative of results that can be expected for a full year.

(b) Use of estimates and assumptions

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 are the 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.

(c) 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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(d) Derivative liabilities and fair value of financial instruments

The Company s only currently outstanding derivative liability relates to the detachable warrants issued to Silicon Valley Bank (SVB) in relation to a loan that was repaid in March 2014 (see Note 4. Loan facility). 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 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 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 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 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:

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.

(e) 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 Company s initial public offering (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.

(f) Segment reporting

The Company operates in one segment, the identification and development of therapeutics in disease areas of inflammation and immune-oncology. 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 long-term investments, were $112,162 as of September 30, 2015 (December 31, 2014 $31,099).

(g) 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.

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(h) Recently issued and recently adopted accounting standards

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.

In April 2015, the FASB issued ASU 2015-03 Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs which changes the presentation of debt issuance costs in the balance sheet to be a direct deduction from the related debt liability rather than as an asset. ASU 2015-03 is effective for fiscal years beginning after December 31, 2015, and interim periods within those fiscal years. Early adoption permitted for financial statements that have not been previously issued. The Company does not anticipate a material impact to the Company s financial statements as a result of this change.

In August 2015, the FASB issued ASU 2015-15 Interest Imputation of Interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements (Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting). The guidance issued previously in ASU 2015-03 did not address presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements. Given the absence of authoritative guidance within ASU 2015-03, the SEC staff stated that they would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The Company does not anticipate a material impact to the Company s financial statements as a result of the amendments.

(i) 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 $105,613 as of September 30, 2015, may never become profitable and expects to 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 will require additional capital to finance its future 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;

- the Company s ability to obtain favorable results in its anticipated clinical trials for AQX-1125 in bladder pain syndrome/interstitial cystitis (BPS/IC);

SHIP1 has not been validated as a target and to date, no drug which specifically targets SHIP1 has been approved by any regulatory authority for the treatment of disease;

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, government agencies, and public and private research institutions, among others.

3. Cash and cash equivalents

	SEPTEMBER 30, 2015	DECEMBER 31, 2014
Cash	$ 92,980	$ 8,351
Cash equivalents	16,393	6,555
	$ 109,373	$ 14,906

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4. Loan facility

On October 23, 2013, AQXP Canada entered into a term loan facility with SVB for up to $4,000, of which $2,500 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 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 at $10.56 per share. These warrants expire in 2023.

On March 28, 2014, AQXP Canada made a cash payment of $2,610 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 $214 along with the prepayment penalty, repayment fee and accrued interest were recorded within bank charges and financing costs.

5. Stockholders equity

(a) Share capital

Aquinox USA is authorized to issue 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 preferred stock both with a par value of $0.000001 per share. As of September 30, 2015, total number of shares of common stock issued and outstanding was 17,211,986 (December 31, 2014 10,695,108). As of September 30, 2015 and December 31, 2014, no shares of preferred stock were issued or outstanding.

(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 March 6, 2014. The 2014 Plan is the successor to and continuation of the Joint Canadian Stock Option Plan (the 2006 Plan) and 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 at September 30, 2015, the maximum number of shares of common stock that may be issued under the 2014 Plan was 1,271,756 shares. 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 outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors.

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, 2014	824,604	$ 6.79	7.16	$ 789

Options granted	287,750	11.46			
Options exercised	(191,878)	5.99			
Options forfeited	(49,349)	9.58			
Options expired	(12,170)	9.26			
Outstanding at September 30, 2015	858,957	$ 9.72	7.80	$	3,736
Exercisable at September 30, 2015	152,802	$ 9.29	6.37	$	2,231

During the nine months ended September 30, 2015, the Company granted 257,750 stock options to employees and 30,000 stock options to directors. The stock options granted to employees during the nine months ended September 30, 2015 have exercise price per share ranging from $7.45 to $12.03 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 non-employee directors during the nine months ended September 30, 2015 have an exercise price per share of $12.03 and have vesting period of either (i) one year at equal monthly installment from the beginning of the vesting period or (ii) three years at equal annual installments from the beginning of the vesting period. All stock options under the 2014 Plan are subject to a 10 year expiration period.

During the nine months ended September 30, 2015, 191,878 shares of common stock were issued upon exercise of options.

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(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:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014	2015	2014
Expected volatility	NA	108%	98%	108%
Expected dividends	NA	0%	0%	0%
Expected terms (years)	NA	6.00	6.40	6.00
Risk free rate	NA	1.70%	1.48%	1.67%
Weighted average grant-date fair value of stock options	NA	$6.16	$9.02	$8.33

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. Stock-based compensation expense charged to income for the plans was $424 and $1,145 for the three and nine months ended September 30, 2015, respectively and $233 and $585 for the three and nine months ended September 30, 2014, respectively. As of September 30, 2015, total unrecognized compensation cost for all stock-based compensation plans was $3,513 (September 30, 2014 $2,982), which is expected to be recognized over a weighted-average period of 2.76 years (September 30, 2014 2.87 years). No stock options were granted for the three months ended September 30, 2015.

(d) Public offering

On September 15, 2015, the Company completed an underwritten public offering of 6,325,000 shares of its common stock (inclusive of 825,000 shares issued pursuant to the underwriters exercise of their option to purchase additional shares) at a price to the public of $15.50 per share. The Company received gross proceeds of approximately $98.0 million before underwriting commissions and expenses of approximately $6.2 million.

6. Net loss per share

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 net 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 and common stock warrants were excluded from the calculation of basic and

diluted net loss per share as the effect would have been anti-dilutive. There were no outstanding preferred stock for the three and nine months ended September 30, 2015 and 2014. The detail of the computation of basic and diluted net loss per share is as follows:

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	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014	2015	2014
Numerator				
Net loss	$ (5,035)	$ (6,284)	$ (16,197)	$ (15,937)
Accretion for liquidation preference on preferred stock				(1,133)
Accretion for share issuance costs on preferred stock				(20)
Tax expense on preferred stock				(100)
Reversal of tax payable on preferred stock due to conversion of preferred stock				1,898
Extinguishment of remaining share issuance costs due to conversion of preferred stock				(439)
Total loss attributable to common stockholders	$ (5,035)	$ (6,284)	$ (16,197)	$ (15,731)
Denominator				
Weighted average shares used to compute basic and diluted net loss per common share	11,841,147	10,695,042	11,096,369	7,984,052
Net loss per share attributable to common stockholders basic and diluted	$ (0.43)	$ (0.59)	$ (1.46)	$ (1.97)

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014	2015	2014
Outstanding stock options	858,957	813,358	858,957	813,358
Common stock warrants	11,363	11,363	11,363	11,363
	870,320	824,721	870,320	824,7212

7. 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:

September 30, 2015

Short-term investments:	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. treasury securities	$ 6,034	$ 2	$	$ 6,036
U.S. government agency securities	2,001	1		2,002
	$ 8,035	$ 3	$	$ 8,038
Contractual maturities:				
Due within one year	$ 8,035			$ 8,038

The Company had no long-term investments consisting of available-for-sale securities on September 30, 2015.

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December 31, 2014

Short-term investments:	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. treasury securities	$ 12,199	$	$ (5)	$ 12,194
U.S. government agency securities	11,996	1		11,997
	$ 24,195	$ 1	$ (5)	$ 24,191
Long-term investments:				
U.S. government agency securities	$ 2,003	$ 0	$	$ 2,003
Contractual maturities:				
Due within one year	$ 24,195			$ 24,191
Due after one year through two years	2,003			2,003

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	$ 12,194	$ (5)	NA	NA
September 30, 2015	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 held short and long-term investments that are classified as available-for-sale securities, which were 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 September 30, 2015				
Short-term investments U.S. treasury securities	$ 6,036	$	$	$ 6,036
Short-term investments U.S. government agency securities	2,002			2,002
Bank loan warrant derivative liabilities			(142)	(142)
	$ 8,038	$	$ (142)	$ 7,896
BALANCES December 31, 2014				
Short-term investments U.S. treasury securities	$ 12,194	$	$	$ 12,194
Short-term investments U.S. government agency securities	11,997			11,997
Long-term investments U.S. government agency securities	2,003			2,003
Bank loan warrant derivative liabilities			(72)	(72)
	$ 26,194	$	$ (72)	$ 26,122

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 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, 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):

Three months ended September 30, 2015:		BANK LOAN WARRANT DERIVATIVE LIABILITIES
BALANCES	June 30, 2015	$ 66
Change in fair value of derivative liabilities		76
BALANCES	September 30, 2015	$ 142

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Nine months ended September 30, 2015:		BANK LOAN WARRANT DERIVATIVE LIABILITIES
BALANCES	December 31, 2014	$ 72
Change in fair value of derivative liabilities		70
BALANCES	September 30, 2015	$ 142

There were no transfers between Levels 1, 2, and 3 during the three and nine months ended September 30, 2015.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto included elsewhere in this report and our audited consolidated and combined financial statements and notes included as part of our Annual Report on Form 10-K for the year ended December 31, 2014.

Forward-Looking Statements

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934. 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 and financial guidance. 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 document 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. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption Risk Factors set forth in Item 1A of Part II of this quarterly report on Form 10-Q, as well as those contained from time to time in our other filings with the SEC. 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 (SH2-containing inositol-5 -phosphatase 1), 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, which is a regulating component of the PI3K cellular signaling pathway. By increasing SHIP1 activity, AQX-1125 accelerates a natural mechanism that has evolved to maintain homeostasis of the immune system and reduce immune cell activation and migration to sites of inflammation. AQX-1125 has demonstrated preliminary safety and favorable drug properties in multiple preclinical studies and clinical trials. We are currently developing AQX-1125 as an oral, once daily treatment in bladder pain syndrome/interstitial cystitis (BPS/IC). 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 other SHIP1 activator has to date reported data from clinical trials or 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 (IPO) in March 2014, AQXP Canada became a wholly owned subsidiary of Aquinox USA.

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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 September 30, 2015, we had $117.4 million in cash, cash equivalents and short-term investments in liquid, high-quality securities.

Since inception, we have incurred significant operating losses. Our net losses for the three and nine months ended September 30, 2015 were $5.0 million and $16.2 million, respectively. This compared to $6.3 million and $15.9 million for the three and nine months ended September 30, 2014. As of September 30, 2015, we had an accumulated deficit of $105.6 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and, if successful, to potentially seek regulatory approval for AQX-1125 and any future product candidates we advance to clinical development. If we are able to 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 considerable financial and management resources, some of which would have to be deployed prior to having any certainty of marketing approval.

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.

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 three and nine months ended September 30, 2015 and 2014 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2015	2014	2015	2014
Research and development	$ 3,687	$ 5,323	$ 11,873	$ 11,754
General and administrative	1,230	987	3,874	2,803
Total operating expenses	$ 4,917	$ 6,310	$ 15,747	$ 14,557

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Research and Development Expenses

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.

Our main clinical activities are described as follows:

Leadership Trial

The Leadership trial was a multicenter, randomized, double-blind, placebo-controlled, Phase 2 clinical trial investigating the ability of 200 mg oral, once daily AQX-1125 to reduce pain and urinary symptoms in female patients with BPS/IC. BPS/IC is a chronic inflammatory bladder disease characterized by bladder pain and increased urinary urgency and/or frequency. The primary endpoint was 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 electronic diary. The trial was conducted at investigative sites across Canada and the United States. A total of 69 subjects were enrolled.

While the top line trial results announced in June 2015 demonstrated a reduction in pain for patients on AQX-1125 as compared to those patients on placebo following six weeks of treatment, the difference did not reach statistical significance ($p = 0.061$). The mean change in pain score for patients on 200 mg oral, once daily AQX-1125 vs. placebo was a reduction of 2.4 vs. 1.3 points, respectively. The primary endpoint was based on an 11-point numeric rating scale recorded by electronic diary. Approximately 49% of patients receiving AQX-1125 demonstrated a 2-point or greater reduction in pain compared to 34% of patients receiving placebo. Subsequent results from pre-specified secondary endpoints of the Leadership trial, such as maximum daily pain, O Leary-Sant Symptom and Problem Index, Bladder Pain Interstitial Cystitis Symptom Score (BPIC-SS) and urinary frequency, were consistently favorable for AQX-1125. Such secondary endpoints included a statistically significant 1.3 point greater reduction over placebo on maximum daily pain at six weeks ($p = 0.030$) and a statistically significant 4.4 point greater reduction over placebo on the O Leary-Sant Symptom and Problem Index at six weeks compared to placebo ($p = 0.008$), and we believe these

results support further development in BPS/IC. As with past trial results, AQX-1125 was generally well tolerated. No serious adverse events were recorded during the trial and the overall adverse event rate was similar between AQX-1125 and placebo. The most frequently reported adverse events were gastrointestinal disorders (32% for AQX-1125 vs. 34% for placebo).

We intend to proceed with further development of AQX-1125 in BPS/IC, including finalizing pivotal trial designs to support product registration in consultation with the appropriate regulatory authorities. We intend to hold an end of Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2015. Subject to input by the FDA and other regulatory authorities, including with respect to the satisfactory completion of Phase 2, we anticipate conducting two pivotal trials of AQX-1125 in BPS/IC, with the first pivotal trial commencing in 2016, and designed as a 12 week trial at multiple varying doses, with a potential open label extension. We anticipate the second pivotal trial would be at a single dose determined based on the outcome of the first pivotal trial.

Flagship Trial

The Flagship trial was a multicenter, randomized, double-blind, placebo-controlled, Phase 2 clinical trial investigating the ability of 200 mg, oral, once daily AQX-1125 to reduce the effects of exacerbations in 400 unstable patients with moderate to severe chronic obstructive pulmonary disease (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. The primary endpoint was the change in the severity, duration and recurrence of COPD exacerbations in patients treated with AQX-1125 versus placebo, as measured by EXACT, a patient-reported outcome tool that measures symptoms. The Flagship trial was initiated in December of 2013 and enrolled subjects at investigative sites across Northern and Central Europe, Australia, New Zealand and the United States.

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On July 9, 2015, we announced top line results of the Flagship trial. The Flagship trial failed to demonstrate efficacy in COPD patients with a history of frequent exacerbations. In the trial, patients treated with 200 mg oral, once daily AQX-1125 for 12 weeks demonstrated no difference in COPD symptoms compared to placebo, as measured by EXACT. On the secondary endpoint of medically treated exacerbations there was also no benefit observed with AQX-1125. Consistent with past AQX-1125 trial results, AQX-1125 was generally well tolerated in the Flagship trial. The overall adverse event rate was similar between AQX-1125 and placebo. We are currently not planning further development of AQX-1125 as a potential treatment for COPD.

Kinship Trial

The Kinship trial was a multicenter, randomized, double-blind, placebo-controlled, Phase 2 clinical trial investigating the ability of AQX-1125 to reduce characteristic symptoms in 54 patients with mild to moderate atopic dermatitis (AD). AD is an inflammatory, relapsing and itchy skin disorder that is often chronic in nature. The Kinship trial was initiated in December 2014 and enrolled subjects at clinical research centers in Canada. On November 2, 2015, we announced that patients treated with 200 mg oral, once daily AQX-1125, compared to placebo, did not meet the primary endpoint of improvement from baseline in Total Lesion Symptom Score after 12 weeks of treatment and the results do not warrant further development for this indication. The Kinship trial demonstrated AQX-1125 to be well tolerated and adverse events were consistent with prior clinical trials. No serious adverse events were recorded during the trial.

Overall, research and development expenses for the three months ended September 30, 2015 declined to $3.7 million, compared to $5.3 million for the three months ended September 30, 2014. The decline was the result of reduced expenditures as we complete final activities related to the Leadership and Flagship trials. For the nine months ended September 30, 2015, research and development expenses totaled $11.9 million, compared to $11.8 million for the nine months ended September 30, 2014. The increase was primarily the result of activities associated with the Kinship clinical trial but partly offset by declining activities associated with the Flagship and Leadership trial. As we continue our development of AQX-1125, particularly in BPS/IC, we expect to incur progressively higher research and development expenses in the foreseeable future.

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 three and nine months ended September 30, 2015, general and administrative expenses totaled approximately $1.2 million and $3.9 million, respectively. This compared to $1.0 million and $2.8 million for the three and nine months ended September 30, 2014, respectively. General and administrative expense for the three months ended September 30, 2015 was higher compared to the same period in 2014 primarily due to higher personnel related costs and legal expenses. For the nine months ended September 30, 2015, the increase compared to the same period in 2014 was the result of additional costs associated with being a public company as we completed our IPO in March 2014. Prior to the IPO, we had lower costs for insurance, personnel, consultants, legal and travel.

Bank charges and financing costs

Bank charges and financing costs consist of normal course bank charges, bank loan interest and warrant discount amortization. For the three month periods ended September 30, 2015 and 2014, the bank charges and financing costs

were immaterial, consisting only of normal course bank charges. For the nine month period ended September 30, 2015, bank charges and financing costs were also immaterial. This compared to $0.4 million for the nine months ended September 30, 2014 when we incurred early repayment penalty and fees of $0.1 million and accretion of warrant discount and deferred costs of $0.3 million resulting from early repayment in March 2014 of a term loan with Silicon Valley Bank.

Change in fair value of derivative liabilities

Derivative liabilities are re-measured at each balance sheet date with the corresponding change recorded within change in fair value of derivative liabilities. There was no material change in fair value for the three and nine months ended September 30, 2015 and the three months ended September 30, 2014. There was a $0.9 million change in fair value for the nine months ended September 30, 2014 when, 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, resulting in a decline in our derivative liabilities.

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Amortization and extinguishment of remaining discount on preferred stock

No amortization or extinguishment of discount related to preferred stock occurred in the three and nine months ended September 30, 2015 and in the three months ended September 30, 2014. For the nine months ended September 30, 2014, the amortization and extinguishment of discount on preferred stock of $1.9 million 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.

Other income (expenses)

Other income (expenses) include primarily interest income and foreign exchange gains and losses. For the three months ended September 30, 2015 and September 30, 2014, we had an immaterial amount of other expenses. Expenses for both periods were primarily the result of foreign exchange losses. For the nine months period ended September 30, 2015, we recorded $0.4 million of other expenses primarily as a result of foreign exchange losses on our foreign currency holdings as the U.S. dollar strengthened during that period. For the nine months ended September 30, 2014, the other income was immaterial.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Our operating activities used $16.8 million of cash flows during the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of $105.6 million, working capital of $114.1 million and cash, cash equivalents and short-term investments of $117.4 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2015 and 2014 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2015	**2014**
Net cash (used in) provided by:		
Operating activities	$ (16,776)	$ (10,792)
Investing activities	18,147	(29,624)
Financing activities	93,096	45,279
Increase in cash and cash equivalents	$ 94,467	$ 4,863

Net cash used in operating activities

The increase in net cash used in operating activities for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was driven by an increase in clinical development expenses.

Net cash provided by (used in) investing activities

Net cash provided by investing activities for the nine months ended September 30, 2015 consisted primarily of the maturity of short-term investments. The net cash used in investing activities during the nine months ended September 30, 2014 resulted from the investment of the cash proceeds received from our IPO in March 2014.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2015 resulted from the public offering of common shares in September 2015 for gross proceeds of $98.0 million, offset by $6.1 million of offering costs, and proceeds from the exercise of stock options of $1.1 million. For the nine months ended September 30, 2014, net cash provided by financing activities was the result of the $53.1 million in proceeds from our IPO in March 2014, offset by $5.3 million of offering costs and the repayment of a bank loan with Silicon Valley Bank for $2.6 million.

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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 continue our development of AQX-1125 in BPS/IC, as well as other clinical and 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:

- our planned pivotal trials of AQX-1125 in BPS/IC and any other future 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;
- the cost of commercialization activities if AQX-1125 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any;
- 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 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 Part II of this Quarterly Report titled Risk Factors for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC. There have been no material changes from the contractual commitments previously discussed in that Annual Report on Form 10-K.

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 in our consolidated financial statements. 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. A summary of our significant accounting policies is presented in Part II, Item 8, of our Annual Report on Form 10K for the year ended December 31, 2014. There have been no material changes to our significant accounting policies during the nine months ended September 30, 2015.

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Recent Accounting Pronouncements

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.

In April 2015, the FASB issued ASU 2015-03 Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. , which changes the presentation of debt issuance costs in the balance sheet to be a direct deduction from the related debt liability rather than as an asset. ASU 2015-03 is effective for fiscal years beginning after December 31, 2015, and interim periods within those fiscal years. Early adoption permitted for financial statements that have not been previously issued. We do not anticipate a material impact to our financial statements as a result of this change.

In August 2015, the FASB issued ASU 2015-15 Interest Imputation of interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements (Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting). The guidance issued previously in ASU 2015-03 did not address presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements. Given the absence of authoritative guidance within ASU 2015 -03, the SEC staff stated that they would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The Company does not anticipate a material impact to the Company s financial statements as a result of the amendments.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Management believes there have been no material changes to our quantitative and qualitative disclosures about market risks during the nine months ended September 30, 2015, compared to those discussed in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC.

Market Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. As of September 30, 2015, we had holdings in U.S. government securities of $24.1 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 $0.02 million in the fair value of our investment portfolio as of September 30, 2015.

Foreign Currency Risk

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. For the three months ended September 30, 2015, we have an immaterial amount of foreign exchange gain. For the nine months ended September 30, 2015, we incurred foreign exchange losses of $0.4 million as a result of the

strengthening of the U.S. dollar against our foreign currency portfolio. We currently do not hedge against foreign currency risk.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on management s evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

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Changes in internal control over financial reporting. There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the most recent fiscal quarter covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. We have marked with an asterisk (*) those risk factors below that reflect significant changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2014.

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 and 2013, and for the nine months ended September 30, 2015, we reported net losses of $24.0 million, $8.7 million and $16.2 million, respectively. As of September 30, 2015, we had an accumulated deficit since inception of $105.6 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue the research and development of, and potentially 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.

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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;

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. For example, we did not meet the primary endpoints in our Leadership, Flagship or Kinship trials. 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;

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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, 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;

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 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 to continue to incur substantial research and clinical development expenses 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, cash equivalents and short term investments 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.

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If we need to secure additional financing, 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.

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.

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Raising additional capital may cause dilution to our 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 our 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, this could result in dilution to our 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 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 is uncertain and could be limited.*

To the extent that our taxable income in a year exceeds any operating losses in such year, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, our ability to use our NOL carryforwards is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. In addition, 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 change in our ownership by certain 5-percent shareholders that exceeds 50 percentage points over a rolling 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, as a result of historical or future equity offerings and/or other changes in our stock ownership, some of which are outside our control. 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 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, as a result of the exchange of shares of AQXP Canada for shares of Aquinox USA, there may be limitations on AQXP Canada s ability to use its various tax attributes following the acquisition of control. In general, an acquisition of control would result in (1) AQXP Canada losing all of its net capital loss carryforwards, if any, and (2) AQXP Canada s non-capital loss carryforwards and other similar tax attributes only being useable thereafter 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 from a business 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 from a business 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.

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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 may utilize numerous clinical trial sites in various countries outside of the United States as part of our clinical trials for AQX-1125 or future product candidates. These clinical trial sites would 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 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 for which we recently announced top line data for three 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. As a result of the outcome of our Flagship and Kinship trials, we are currently not planning further development of AQX-1125 for the treatment of COPD or AD and therefore our near-term prospects are largely dependent on our ability to obtain favorable results from our anticipated clinical trials for AQX-1125 in BPS/IC. 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 pivotal 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 the marketing of AQX-1125 or 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 candidates 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.

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Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results, AQX-1125, 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. For example, despite showing positive results in our COPD proof-of-concept trial following a lipopolysaccharide (LPS) challenge in healthy subjects, our Phase 2 Flagship clinical trial with AQX-1125 failed to demonstrate efficacy in COPD patients with a history of frequent exacerbations. In addition, our Phase 2 Leadership clinical trial in BPS/IC failed to demonstrate statistically significant results in its primary endpoint and our Phase 2 Kinship clinical trial failed to demonstrate efficacy in patients with mild to moderate AD. 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.

We have not yet established the optimal dose for AQX-1125. There can be no guarantee that the 200 mg dose studied in our Phase 2 clinical trials will be efficacious or, if it is, whether it will be the optimal dose in future clinical trials. 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. 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;

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;

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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

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

As an organization, we have never conducted a pivotal 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.*

Based on the results of our Leadership trial, we intend to discuss potential pivotal trial designs for AQX-1125 in BPS/IC with the FDA and other regulatory agencies, prior to undertaking those trials alone or with a future collaborator. The FDA may not agree that Phase 2 development is complete and may recommend or require that we conduct one or more additional Phase 2 trials before conducting pivotal trials. The conduct of pivotal clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not conducted a pivotal 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 yet discussed our proposed regulatory approval strategy with the FDA. 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. 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.

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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 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 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 candidates, 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 yet discussed our proposed regulatory approval strategy with them. 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 pivotal 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.

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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 completely or partially 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 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, Flagship and Kinship 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 and patients have experienced limited adverse events, the most frequent of which were gastrointestinal disorders, 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 completed clinical trials is mild gastrointestinal upset including mild diarrhea, nausea and gastric pain. 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, subsequently 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;

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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 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.

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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.

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.

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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. 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 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 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. 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.

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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. 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.

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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 or entities from knowingly and willfully soliciting, offering, receiving, providing or 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;

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the 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 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 statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 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 Payments 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; 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 internal operations and 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 laws and 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.

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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 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, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners 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 fraud or other misconduct by our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners, 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 data privacy, security, fraud and abuse and other healthcare 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. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause 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 misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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.

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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 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 field of BPS/IC, 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 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.

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.

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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 $10 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 September 30, 2015, we had 21 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;

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.

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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.

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, cyber attacks, 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.

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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 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.

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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. Although we are currently working with a separate CMO to develop a bioequivalent tablet formulation of AQX-1125 for potential use in our planned future clinical trials, there can be no assurance that we will be successful in such efforts. 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 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.

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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 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.

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The USPTO has developed new and untested 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. While we cannot predict with certainty theimpact the Leahy-Smith Act will have on the operation of our business, 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/or 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 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.

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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.

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.

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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, since January 1, 2015, our common stock s sales price on The NASDAQ Global Market has ranged from a low of $1.38 to a high of $55.75. As of November 6, 2015, the closing price on The NASDAQ Global Market of our common stock was $14.00 per share. 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. 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.

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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. For example, on July 8, 2015, the closing price of our common stock on The NASDAQ Global Market was $6.55, and on July 9, 2015, following our announcement of negative results from our Phase 2 Flagship clinical trial in COPD, the closing price was $2.13. 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 majority of our outstanding voting stock. In particular, based on information available to us, Baker Bros. Advisors LP and its affiliates, which together are our largest stockholders, beneficially owned approximately 39.6% of our common stock as of September 11, 2015. Stockholders which control the voting of a majority of our shares of common stock are able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders are 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 are taking 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 are taking 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 have taken and 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.

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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 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.

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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. The increased costs will increase our consolidated net loss. 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.

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. We have also filed a registration statement covering the sale of up to $150.0 million of any combination of our common stock, preferred stock, debt securities or warrants. On September 15, 2015, we closed a public offering of 6,325,000 shares of our common stock at a price to the public of $15.50 per share for gross proceeds of approximately $98.0 million before underwriting discounts and commissions and offering expenses. The amount of our common stock, preferred stock, debt securities or warrants that we may issue pursuant to the abovementioned registration statement was reduced by the amount of this offering, as this offering was conducted pursuant to such registration statement. We may conduct additional sales of securities pursuant to such registration statement, from time to time.

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 your percentage ownership 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 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.

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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, Chief Executive Officer 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 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

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 continue to use the proceeds of this offering to conduct Phase 2 clinical trials to evaluate AQX-1125, 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 September 30, 2015, we had used approximately $22.4 million of the proceeds from our IPO.

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Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of Aquinox Pharmaceuticals, Inc.
3.2(2)	Amended and Restated Bylaws of Aquinox Pharmaceuticals, Inc.
4.1(3)	Specimen Common Stock Certificate of the Aquinox Pharmaceuticals, Inc.
4.2(2)	Warrant to Purchase Stock of Aquinox Pharmaceuticals, Inc., issued to Silicon Valley Bank, dated October 23, 2013.
4.3(2)	Amended and Restated Qualification and Registration Rights Agreement of Aquinox Pharmaceuticals, Inc., dated March 19, 2013.
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1+	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS+	XBRL Instance Document
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 Labels Linkbase Document.
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document.

+ Filed herewith.

(1) Previously filed as an exhibit to the Registrant s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2014 (File No. 001-36327) and incorporated herein by reference.

(2) Previously filed as an exhibit to the Registrant s Registration Statement on Form S-1, as amended (File No. 333-193615), filed with the Securities and Exchange Commission on January 28, 2014 and incorporated herein by reference.

(3) Previously filed as an exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed with the Securities and Exchange Commission on May 13, 2014 (File No. 001-36327) and incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements 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.
(Registrant)

Date: November 10, 2015

/s/ David J. Main
David J. Main
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2015

/s/ Kamran Alam
Kamran Alam
Chief Financial Officer
(Principal Financial and Accounting Officer)

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101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document.
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