

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

December 18, 2013

Via E-mail
David J. Main
President and Chief Executive Officer
Aquinox Pharmaceuticals Inc.
430-5600 Parkwood Way
Richmond, B.C., Canada V6V 2M2

Re: Aquinox Pharmaceuticals (USA) Inc.
Draft Registration Statement on Form S-1
Submitted November 18, 2013
CIK No. 0001404644

Dear Mr. Main:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### General

- 1. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 2. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

# <u>Prospectus Summary</u> Our Pipeline, page 1

- 3. Please explain the terms "lipopolysaccharide (LPS) challenge" and "sputum neutrophils" in this discussion.
- 4. Please explain what the p-values you cite in your discussion represent and what p-values constitute a statistically significant result in your clinical trials.

#### Risks Associated to Our Business, page 3

5. In your first bullet point, please include your accumulated deficit to date.

# <u>Summary Combined Financial Data</u> <u>Combined Balance Sheet Data, page 9</u>

- 6. It appears that your pro forma total stockholders' deficit at September 30, 2013 should be a positive number and result in pro forma total stockholders' equity. Please revise. This comment also applies to your presentation in Selected Combined Financial Data on page 55.
- 7. You disclose in footnote 3 that the balance sheet pro forma as adjusted basis excludes any impact of the term loan facility with Silicon Valley Bank ("SVB") you entered into on October 23, 2013 for up to \$4.0 million of which \$2.5 million was received on October 30, 2013. It appears that this debt is material and should be presented in the pro forma as adjusted column. Please revise or explain to us why this event is not material to investors. Please refer to Rule 11-01(a)(8) of Regulation S-X. This comment also applies to your presentation in Capitalization on page 49 and Selected Combined Financial Data on page 55.

# Risk Factors General

8. We note that your disclosure on page 84 and 86 of the registration statement that your Phase 2 clinical trials for AQX-1125 in COPD and BPS/IC will be conducted in Northern and Central Europe and Canada, respectively. Please revise your disclosure to include a separate risk factor which highlights this disclosure and discusses any risks the Company may face as a result of the conduct of clinical trials outside of the United States. For example, you should discuss the possibility that the FDA may not accept the results of such trials and how such lack of acceptance could impact the regulatory approval process.

#### Risks Related to Our Business and Industry

"Because the results of preclinical testing or earlier clinical trials are not necessarily predictive of future results . . .," page 15

9. Please explain in this risk factor how EXACT-PRO functions and clarify that the primary endpoint in the clinical trial is the change in the severity, duration and reoccurrence of

exacerbations in patients as measured by EXACT-PRO. Further, please note here, as you have on page 85, that you are not aware of any instance where EXACT scores have been accepted as endpoints in a Phase 2 or Phase 3 trial.

10. Please specify how endpoints measured using EXACT-PRO differ from accepted clinical COPD endpoints.

# "SHIP1 has not been validated as a target," page 16

11. Please briefly explain the ramifications of not yet having been validated as a target and describe the process of target validation.

"Our future success depends on our ability to attract, retain and motivate qualified personnel," page 30

12. Please include in this risk factor the name(s) of the member(s) of your management team, or any other personnel, whose departure you believe would have the potential of creating a material adverse effect.

#### Risks Related to Our Dependence on Third Parties

"We have no experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility . . .," page 32

13. Here, and in your Manufacturing discussion on pages 92-93, please identify your single source CMOs for the manufacture of AQX-1125's active pharmaceutical ingredient and for the final product formulation.

#### Special Note Regarding Forward-Looking Statements and Industry Data, page 44

14. We note your statements that "we have not independently verified market and industry data from third-party sources" and that your internal company research or market definitions have not been validated by any independent source. Please amend your registration statement to remove these statements as it is not appropriate to directly or indirectly disclaim liability for information in your filing.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates

Stock-Based Compensation, page 68

15. Please expand your disclosure to disclose the intrinsic value of outstanding vested and unvested options based on the estimated IPO price and the options outstanding as of the most recent balance-sheet date presented. Also include a discussion of each significant factor contributing to the difference between the fair value as of the date of each grant and the estimated IPO price.

## Fair Value Estimates, page 69

16. You disclose that you are required to estimate the fair value of the common stock underlying their stock-based awards when performing the fair value calculations using the intrinsic value method at each reporting date. Based on your disclosure in the subsequent paragraphs it appears that you can reasonably estimate the fair values as of each grant date and the use of the intrinsic value method is not appropriate. Please revise your disclosure to remove any reference to the use of the intrinsic value method or explain to us why the intrinsic value method is appropriate. Please refer to ASC 718-10-30-21.

#### **Business**

## AQX-1125, page 78

- 17. In your discussion of AQX-1125's desirable pharmaceutical properties, please define the terms "linear elimination," "consistent half-life," and "dose proportional exposure."
- 18. In your description of AQX-1125's preclinical inflammatory studies, please explain what neutrophils, eosinophils and macrophages are.

### Choice of Forum, page 126

19. We note your disclosure entitled Choice of Forum on page 126. Several lawsuits are currently challenging the validity of choice of forum provisions in certificates of incorporation. Please disclose that although you will provide a choice of forum clause in your restated certification of incorporation, it is possible that a court could rule that such provision is inapplicable or unenforceable.

# <u>Combined Financial Statements</u> Combined Balance Sheets, page F-7

20. Your pro forma deficit accumulated in the development stage line item here does not agree with the amount disclosed on page F-6. Please revise to eliminate all inconsistencies.

## Item 16. Exhibits and Financial Statement Schedule, page II-3

21. Please file the agreement underlying your term loan facility with Silicon Valley Bank as an exhibit to the registration statement.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

letters to you.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your

confidential submissions to us so we do not repeat or refer to that information in our comment

You may contact Donald Abbott at (202) 551-3608 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler Assistant Director

cc: Michael E. Tenta
Gordon H. Empey
Cooley LLP
1700 Seventh Avenue, Suite 1900
Seattle, WA 98101