

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

September 12, 2013

<u>Via- Email</u>
Ms. Karen Corraini
General Counsel and Corporate Secretary
Xenon Pharmaceuticals Inc.
200 – 3650 Gilmore Way
Burnaby, British Columbia V5G 4W8, Canada

Re: Xenon Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted August 16, 2013
CIK No. 0001582313

Dear Ms. Corraini:

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 file all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Prior to its use please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. 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.

4. Comments to your application for confidential treatment will be delivered under separate cover.

# Overview, page 1

5. We note that you state that you have three development-stage product candidates. Please identify the two development-stage product candidates that are pre-clinical.

# Our Programs, page 2

- 6. We note on page 2 that uniQure is preparing to apply for regulatory approval for Glybera in the U.S. Please expand your disclosure to discuss the timeline for applying for U.S. approval. If any regulatory issues or other factors have caused uniQure to delay filing an NDA with the FDA or an NDS with Health Canada, please provide appropriate disclosure.
- 7. The first time you refer to the terms "antisense oligonucleotide" and "hepcidin," please explain how each functions in the human body.

#### Our Extreme Genetics Discovery Platform, page 3

8. Please expand your disclosure on page 3 and 84 to discuss the differences between your Extreme Genetics discovery platform and the methods commonly used by other pharmaceutical companies that are developing products based upon isolating genes or portions of the human genome.

#### Implications of Being an Emerging Growth Company, page 6

- 9. Please disclose your election under Section 107(b) of the Jobs Act:
  - If you have elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act, include a statement that the election is irrevocable; or
  - If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b) of the Jobs Act, provide a risk factor explaining that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please state in your risk factor that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures in MD&A.

# "Recent patent reform legislation and court decisions could increase . . .," page 38

10. Please explain specifically how the Leahy-Smith Act increases uncertainty as to any of your licensed or owned patents. Additionally, please identify any of your licensed or owned patents that may be vacated or adversely affected by the U.S. Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* 

# "We or the third parties upon whom we depend may be adversely affected . . .," page 42

11. Please clarify whether your business interruption insurance applies in the event of an earthquake.

# Cautionary Note Regarding Forward-Looking Statements, page 49

12. Please remove your statement that investors "are cautioned not to give undue weight to such estimates" and the statement that "such information is inherently imprecise." It is not appropriate to directly or indirectly disclaim liability for information in the registration statement.

# Use of Proceeds, page 52

13. We note that you intend to use proceeds of this offering to fund the planned development of XEN701. Please expand your disclosure to state the stage of development of XEN701 you expect to reach using the allocated proceeds.

#### Dilution, page 56

14. Please tell us why you are not subtracting your redeemable convertible preferred shares in your calculation of your historical net tangible book value of as of June 30, 2013.

#### Management Discussion and Analysis of Financial Condition and Results of Operations, 60

15. We note on page 61 and in a risk factor on page 12 that you state that you have not generated substantial royalties on product sales. Please revise your disclosure throughout your prospectus to clarify that you have not generated any revenue from product royalties. Alternatively, please clarify and describe the royalties you have received.

#### Accrued Expenses, page 67

16. Please disclose whether there have been any material adjustments to your estimates of accrued expenses for the periods presented.

# <u>Share-Based Compensation</u> <u>Valuation of Common Shares, page 69</u>

- 17. We have reviewed your share-based compensation disclosures and have the following comments:
  - Please revise your disclosure to state the events that resulted in an increase in the fair value of the common stock from \$0.55 at December 21, 2012 to \$1.07 on January 1, 2013.
  - With respect to the January 1, 2013 valuation report, please clarify whether the blend in the income and market approaches resulted in an equal weighting of both methods.
  - Please update the stock option table on page 70 through the date of effectiveness of your registration statement. Also, please disclose in the filing any new equity issuances such as preferred stock, warrants, etc. through the date of effectiveness.
  - Please note we may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price. Please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value of the most recent issuance.

#### Research and Development Expenses, page 73

18. For your key research and development projects please disclose the costs incurred during each period presented and to date.

# Business, page 81

19. Please amend your disclosure to describe the INDs submitted for XEN402 by indication and disclose when these INDs were filed and by whom. Additionally, please clarify whether you or anyone else has filed INDs for XEN701 or the Selective Inhibitor of Nav1.7 for the Treatment of Pain. If so, provide the same information as requested for the INDs for XEN402.

#### Glybera, page 82

20. Please disclose how you anticipate physicians will prescribe Glybera for patients suffering from LPLD. In particular, please clarify whether you believe doctors will prescribe Glybera for permanent, indefinite, intermittent or short-term use.

#### Programs, page 85

21. We note that you have a collaboration agreement with Teva to develop XEN402 as an inhibitor of Nav1.7. We also note that you have entered into a collaboration agreement with Genentech to develop inhibitors for Nav1.7. Please expand your disclosure to discuss the differences between these two drugs that both inhibit Nav1.7, and the anticipated patient population for each.

# Glybera (alipogene tiparvovec): A Gene Therapy for the Orphan Disease LPLD, page 85

- 22. We note on page 85 that you state that you are eligible to receive a double-digit percentage of all compensation received by uniQure. Please revise this disclosure to provide narrower information about the percentage. For example, you may either provide a range of percentages within ten percent or a statement that the percentage is in the teens, twenties, etc. Additionally, we note that you state that you are eligible to receive mid-single digit royalties from uniQure on page 97. Please include this disclosure on page 85.
- 23. Please quantify the size of the patient population that you and your collaborators are targeting for sales of Glybera.
- 24. Please clarify whether Glybera has orphan designation in the EU.
- 25. We note that you state the results of your Topical XEN402 Phase 2 Trial in EM on page 89. Please indicate the statistical significance of your results by providing a p-value.

# XEN701: An Antisense Oligonucleotide for the Treatment of Anemia of Chronic Kidney Disease, page 94

26. Please quantify the size of the patient population that you plan to target for sales of XEN701.

#### Programs in Discovery, page 96

27. Please quantify the size of the patient population suffering from DS that you plan to target for sales of your small-molecule sodium channel modulators.

#### Strategic Alliances, page 97

- 28. We note that you have a license agreement with Memorial University of Newfoundland on page 76. Please disclose the material terms of this agreement under a separate caption, including the patents licensed under this agreement and how they apply to your products, the duration, material termination provisions, and payment terms and prior payments. Additionally, please file this agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that this agreement is not material to the company.
- 29. Please disclose under a separate caption the payment terms, duration, and material termination provisions of your agreement with the University of British Columbia for your license related to Glybera.

# Agreement with uniQure for Glybera, page 97

- 30. For the uniQure agreement, please disclose the duration of the agreement, the material termination provisions, and when the licensed patents expire.
- 31. We note that you state you will receive a double-digit percentage of all non-royalty compensation that uniQure receives from sublicenses. Please revise your disclosure throughout the registration statement to provide narrower information about the percentage. For example, you may either provide a range of percentages within ten percent or a statement that the percentage is in the teens, twenties, etc.

# Agreement with Teva for XEN402, page 98

32. For the Teva agreement, please disclose the amount of the opt-in fee required for you to have a minority co-promotion interest, the resulting share of the operating profits that you are entitled, and the duration of the agreement. Additionally, please revise your disclosure throughout the registration statement to provide narrower information about the royalty provisions. For example, you may either provide a range of royalties within ten percent or a statement that the percentage is in the teens, twenties, etc.

#### Agreement with Genentech for Selective Inhibitors of Nav1.7, page 99

- 33. Please state the duration of your agreement with Genentech.
- 34. For the Genentech Agreement, we note that you are eligible to receive royalties in the low double-digit range. Please revise your disclosure throughout the registration statement to provide narrower information about the royalty provisions. For example, you may either provide a range of royalties within ten percent or a statement that the percentage is in the teens, twenties, etc.

# Agreement with Merck for Cardiovascular Disease, page 99

- 35. For the Merck Agreement, we note that you are eligible to receive royalties in the high single digit to low double-digit range. Please revise your disclosure regarding the low-double digit range throughout the registration statement to provide narrower information about the royalty provisions. For example, you may refer to a range of royalties within ten percent or state that that the percentage is in the teens, twenties, etc.
- 36. Please state the duration of the agreement with Merck.

#### Research and Development, page 101

37. Please estimate the amount spent on research and development for the past 3 years ending in December 31, 2012 as required by Regulation S-K Item 101(c)(1)(xi).

#### Manufacturing, page 102

38. We note that there are a limited number of suppliers of XEN701, and the inability to find a suitable replacement could materially impact your business. Please expand your disclosure to state your current relationship and the material termination provision of your contractual agreement with your suppliers for XEN701. Additionally, file these agreements as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

# Orphan Drug Designation, page 107

39. Please clarify if the FDA has granted orphan designation to any of your products.

# Government Regulation Outside of the U.S., page 109

40. Please clarify if any of your products have received orphan designation in the EU.

#### **Management**

# Executive Officers, page 115

41. Please expand your disclosure to include Gary Bridger's business experience between December 2007 and June 2010.

#### Indemnification Agreements and Directors' and Officers' Liability Insurance, page 123

- 42. We note that you will enter into indemnification agreements. Please file the form of these agreements as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.
- 43. Please expand your disclosure to explain the limits of indemnification permitted under Canadian law.

#### **Executive Compensation**

# Executive Employment Arrangements, page 125

- 44. Please update your disclosure to include the material terms of the executive employees' amended employment agreements when available.
- 45. Please file the amended employment agreements between the company and each of Dr. Pimstone and Dr. Goldberg as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

# <u>Certain Relationships and Related Party Transactions</u> <u>Consulting Services Provided by Genworks, Inc., page 132</u>

46. If you have a written consulting agreement with Genworks, Inc., please file the agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.

# Shares Eligible for Future Sale, page 149

- 47. Please state the number of shares of common stock that will be restricted securities under Rule 144 upon completion of this offering.
- 48. Once available please file copies of each of the lock-up agreements.

# Notes to Financial Statements 9. Redeemable Convertible Preferred Shares: Conversion, page F-16

49. With respect to the certain adjustments, please revise your disclosure to specifically state the additional events that cause the conversion rate to change, as your reference to "the like" is ambiguous. In addition, please provide us an analysis of whether the conversion option for all preferred stock issued should be a derivative liability.

# 11. Stock Option Plan, page F-17

50. We note that the expected volatility remained at 70% for each of the periods presented. Please tell us why the amount did not change for any period and provide us with your calculation. In addition, clarify how you determined that each public companies used in your determination of expected volatility company was similar. Please also tell us whether the volatility was consistently calculated for each period (i.e. daily, monthly, weekly, etc.).

#### 13. Collaboration Agreements, page F-20

- 51. For your Genome BC arrangement, please revise you disclosure to comply with ASC 605-25-50-2. It is currently unclear what you are collaborating on and what your deliverables are. In addition, please tell us what the counterparty is receiving for funding your research and development beyond the subscription rights. If the consideration is limited to the subscription rights, please explain the economics of the arrangement to us.
- 52. For your Genentech and Teva arrangements please disclose why the licenses did not qualify as separate units of accounting pursuant to ASC 605-25-50-2f. In addition, tell us how your statement that you are unable to estimate a fair value for the undelivered items complies with ASC 605-25-30-2 and how this statement impacts your accounting.
- 53. You disclose several agreements which you are eligible to receive milestone payments. Please revise your disclosure to describe each substantive milestone and the related contingent consideration for each agreement separately. Refer to ASC 605-28-50-2b. In addition, clarify for us why you believe all potential milestone payments under the Merck and Teva agreement are substantive per ASC 605-28-25-2 when you do not appear to be

performing any additional work in the Merck agreement and it is unclear why sales milestones are substantive in the Teva agreement.

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.

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 letters to you.

You may contact Tabatha Akins at (202) 551-3658 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u>
Jeffrey Saper
Wilson Sonsini Goodrich & Rosati, P.C.
650 Page Mill Road
Palo Alto, California 94304