

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

August 7, 2014

Via E-mail
Daniel de Boer
Chief Executive Officer
ProQR Therapeutics B.V.
Darwinweg 24
2333 CR Leiden
The Netherlands

Re: ProQR Therapeutics B.V.

Draft Registration Statement on Form F-1

Submitted July 11, 2014 CIK No. 0001612940

Dear Mr. de Boer:

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. We note that there are a number of additional exhibits that still need to be filed. Please provide these exhibits as promptly as possible. Please note that we may have comments on these materials once they are provided.
- 2. 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.
- 3. 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.

Market and Industry Data, page i

4. We note your statements on page i and page 43 that neither you nor the underwriters "have independently verified any of the data from third-party sources, nor have you or the underwriters ascertained the underlying economic or other assumptions relied upon therein" and "unless otherwise noted, internal analysis and estimates may not have been verified by independent sources." It is not appropriate to directly or indirectly disclaim liability for information in the registration statement. As such, please revise your disclosure to remove any statements indicating that you have not independently verified third-party information or internal analysis and estimates.

Prospectus Summary Overview, page 1

5. We note that AR-010 has been granted orphan drug designation in the United States and the European Union. Please revise your disclosure in this section to indicate the benefits conveyed by orphan drug designation. In addition, please clarify that the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Development of Our Lead Product Candidate, QR-010, in Cystic Fibrosis, page 1

6. Please expand your disclosure to define the term "pharmacokinetics" at its first use in the last paragraph of this section.

Development of Our First Non-CF Program, OR-110, in Leber's Congential..., page 2

- 7. Please expand your disclosure to define the following terms at their first use in this section of the prospectus summary:
 - lymphoblastoid cells;
 - ciliation; and
 - cilium length.

Risk Associated with Our Business, page 3

8. Please revise your summary of material risks to disclose your accumulated deficit to date.

<u>Implications of Being an Emerging Growth Company, page 4</u>

9. Please expand your disclosure to discuss your status as a foreign private issuer and the exemptions available to you as a foreign private issuer. In this regard, please identify those exemptions which overlap with the ones available to you as an emerging growth company and to what extent you will continue to enjoy any exemptions as a result of your status as a foreign private issuer once you no longer qualify as an emerging growth company.

Risk Factors

Risks Related to Our Capital Needs and Financial Position

We will require additional capital to fund our operations and if we fail to..., page 9

10. Please expand your disclosure in this risk factor to quantify the amount of your cash and cash equivalents.

Risks Related to Our Dependence on Third Parties

If third parties on which we depend to conduct our pre-clinical studied or any..., page 16

11. Please expand your disclosure to describe current Good Manufacturing Practices, or cGMPs, the first time you make reference to them in this section of your prospectus.

Risks Related to Our Intellectual Property

We license patent rights from third-party owners or licensees and if we fail..., page 21

12. This risk factor appears to cover two separate risks, the risk that you will fail to comply with your obligations in your intellectual property licenses and the risk that owners or licensees do not properly or successfully obtain, maintain or enforce the patents underlying such licenses. Please revise your disclosure to separate these two risks into their own appropriately titled risk factors.

We may not be able to protect our intellectual property rights throughout the..., page 24

13. We note your disclosure that many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions and that 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. Please expand your disclosure to identify the foreign countries where you may have difficulties enforcing your patent rights.

<u>Risks Related to the Commercialization of Our Product Candidates</u> We face competition from entities that have developed or may develop..., page 25

14. Please define the term "statistically significant" at its first use in the second paragraph of this risk factor.

Risks Related to Our Business and Strategy

Our ability to use our net operating losses to offset future taxable income..., page 33

15. Please expand your disclosure in this risk factor to quantify your tax loss carry-forwards, to describe the limitations on the use of the carry-forwards and when your carry-forwards begin to expire.

Special Note Regarding Forward-Looking Statements and Industry Data, p. 43

16. Many of the statements in your submission relate to present facts or conditions, rather than to historical facts or future events. In light of this, the second sentence of this section beginning, "All statements contained in this prospectus, other than statements of historical fact...," appears to be overly broad. Please narrow your statement accordingly or remove it.

Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations

Research and development costs, page 53

17. Please provide a quantitative discussion of the nature of research and development expenses for each period presented.

General and administrative costs, page 53

18. Please revise your disclosure to quantify the amount of change due to each factor.

<u>Liquidity and Capital Resources</u> <u>Contractual Obligations and Commitments</u> <u>Commitments, page 56</u>

- 19. Please expand your disclosures to include the amount of the potential future milestone payments.
- 20. Please confirm whether the commitments related to the development of QR-010 due in 2014 have been recorded as liabilities in the financial statements.
- 21. Please expand your disclosure in this section to describe the "commitments related to the development of QR-010 amounting to 953,000 euros, all of which is due in 2014."

<u>Critical Accounting Policies and Significant Judgments and Estimates</u> <u>Research and Development Expense, page 58</u>

22. Please revise your disclosure to state whether adjustments to prior period estimates have been material for each period presented and if so please quantify the amounts.

<u>Share-Based Compensation</u> Valuation of our ordinary shares, page 60

23. We may have additional comments on your accounting for stock compensation or any beneficial conversion features once you have disclosed an estimated offering price. Please provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

Business

Overview, page 63

24. We note that you have had a pre-IND meeting with the FDA and scientific advice and protocol assistance meetings with the EMA for QR-010. Please expand your disclosure to summarize the nature of the discussions, relevant feedback from the FDA and EMA and other material information that was communicated among the parties.

QR-010 Increases CFTR Activity in Ex Vivo Primary Lung Cells from CF..., page 71

25. Please expand your disclosure regarding the Ussing Chamber assay to describe the QR-010 dosing used, the primary and any secondary endpoints of the study and how the results of the assay compared to the goals of the study.

NPD Measurements in F508-CFTR Mice, page 72

26. Please expand your disclosure regarding the NPD testing to disclose the primary and secondary endpoints of the test and how the results of the test compared to the endpoints. In this regard, we note that for the mice treated with six doses each of QR-010 over 14 days, CFTR activity in the treated mice increased significantly. As part of your enhanced disclosure and explanation of how the actual results of the test compared to the endpoints, please quantify what you mean when you state that CFTR activity increased significantly and explain what constitutes a significant increase.

QR-010 Improves Saliva Secretion in F508-CFTR Mice, page 73

27. Please expand your disclosure regarding the saliva secretion assay to describe the QR-010 dosing used, the duration of the assay, the primary and secondary endpoints of the assay and how the results of the assay compared to the endpoints.

Other Research and Development Leber's Congenital Amaurosis, page 74

28. Please quantify what you mean when you state that QR-110 "significantly" increased CEP 290 protein levels.

Intellectual Property

Patent Rights Relating to Our Cystic Fibrosis Program, page 75

- 29. Please expand your disclosure to summarize the Patent Cooperation Treaty and how you will rely on it to provide obtain patent protection in various jurisdictions with respect to QR-0101. Please also highlight the type of patent protection you are seeking (e.g. composition of matter, use or process) for your QR-010 product candidate.
- 30. For your patent and patent applications licensed from MGH, please describe the type of patent protection that the issued patent provides and that the patent applications will provide if granted (e.g. composition of matter, use or process).

Facilities, page 93

31. Please file your lease agreement as an exhibit.

Option Plan, page 105

32. Please file your Stock Option Plan and your amended and restated Stock Option Plan as exhibits.

Statement of Comprehensive Loss, page F-4

33. It appears as though you have elected under paragraph 99 of IAS 1 to classify expenses using the function of expense method described in paragraph 103 of IAS 1. However, share-based compensation expense would fall under the nature of expense method under paragraph 102 of IAS 1. Therefore, please revise your presentation to classify share-based compensation expense by functional expense and disclose the share-based compensation expense amounts in the notes to the financial statements rather than on the face of the statement of comprehensive loss.

Notes to the Financial Statements

- 19. Commitments and contingencies
- (c) Patent license agreement, page F-20
 - 34. Please revise your disclosure to include the amounts of the potential milestone payments.

- 21. Events after balance sheet date
- (a) Financing round, page F-22
 - 35. Please disclose the conversion terms of the preferred shares in the event of an initial public offering.

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 Vanessa Robertson at (202) 551-3649 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170, 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: <u>Via E-mail</u>
Mitchell S. Bloom, Esq.
Goodwin Proctor LLP