



DIVISION OF  
CORPORATION FINANCE

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

May 13, 2013

Via E-Mail

Berndt Modig  
Chief Financial Officer  
Prosensa Holding B.V.  
J.H. Oortweg 21  
2333 CH Leiden  
The Netherlands

**Re: Prosensa Holding B.V.  
Confidential Draft Registration Statement on Form F-1  
Submitted April 16, 2013  
CIK No. 0001574111**

Dear Mr. Modig:

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 note that where we provide examples or references to portions of your registration statement to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the registration statement that we have not cited as examples, please make the appropriate changes elsewhere in the registration statement in accordance with our comments.
2. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
3. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If you will use any additional graphic, visual or

photographic information in the printed prospectus, please provide us a proof of each such item for our review prior to its use. Please note that we may have comments regarding this material.

4. 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.
5. We note that you submitted a confidential treatment request on April 17, 2013. We will provide any comments in relation to your confidential treatment request in a separate comment letter.

#### Risk factors

##### Risks related to commercialization of our product candidates

“We rely on obtaining and maintaining orphan drug status....” page 24

6. Please revise the second paragraph of this risk factor to clarify, to the extent you know, whether the EMA has granted Sarepta’s eteplirsen orphan drug status.

“Adverse events in the field of RNA modulation therapy....” page 26

7. To the extent you are aware of adverse events in the clinical trials of other companies developing RNA-modulating products, please revise your disclosure to describe or provide examples of these incidents.

##### Risks related to intellectual property and information technology

“Our business will be adversely affected if we are unable to gain access to relevant intellectual property....” page 29

8. In this risk factor, you reference intellectual property of third parties. We note your discussion of your license with LUMC. To the extent you are substantially dependent on any additional third-party license agreement(s), please expand your discussion in the Business section to describe the material terms of any such agreements and file a copy of any such agreement as an exhibit pursuant to Item 601 of Regulation S-K.

“Issued patents covering one or more of our products could be found invalid....” page 30

9. Please expand this risk factor to include a description of the Sarepta opposition as an example of such proceedings.

Risks related to employee matters and managing growth

“Our future growth and ability to compete depends on retaining our key personnel...,” page 35

10. Please expand this risk factor to identify your key management, scientific and technical personnel.

Risks related to the offering and our ordinary shares

“We may lose our foreign private issuer status...,” page 41

11. Please explain whether the loss of your foreign private issuer status discussed in this risk factor is theoretical or whether you have some actual basis for believing you could in fact lose that status.

Management’s discussion and analysis of financial condition and results of operations

Results of operations—Comparison of the years ended December 31, 2011 and 2012

License revenue, page 59

12. Please disclose what the unconditional milestones payments received under the GSK agreement for the periods presented specifically relate to.

Research and development expense, page 60

13. You present research and development expense by projects (i.e. DMD projects, Non-DMD projects, and infrastructure costs) for the periods presented. On page 57, you indicate that your research and development expense mainly relates to three key programs (i.e. PRO044, PRO045 & PRO053, and other development programs (DMD and Non-DMD projects)). Please revise your disclosure to further disaggregate your project R&D expenses for each of your key programs for each period presented.

Critical accounting policies and significant judgments and estimates

Share-based compensation

Valuation of ordinary shares, page 70

14. To gain a better understanding of your determination of the fair market value of your common stock at each valuation date, please provide us the following information in revised disclosure, as applicable:
  - Disclose the guideline public companies that you selected and what similarities existed between you and the guideline public companies selected such as number of products, types of products, size, working capital, liquidity, etc. Specify any adjustments that were made to reflect differences between you and the public companies selected;
  - Disclose the methodology used to determine your volatility factor from the data obtained for your peer companies;

- Disclose how your cash flow projections were estimated (i.e. products used, period of time, etc.);
  - Regarding the discount applied to both your valuations to reflect the lack of marketability, clarify why the put option analyses was used and if this was the only factor considered in determining the discount; and
  - Tell us what you did prior to and/or at the valuation dates (December 2010 and September 2012) that made you believe there was a 80-85% possibility of a sale of the company and a 15-20% probability of an initial public offering. Explain why these factors remained the same from December 2010 valuation to your September 2012 valuation. Also, tell us why a time to liquidity of 1.5 years is appropriate.
15. Regarding your December 2010 valuation, please revise your disclosure to clarify why you deemed the December 2010 valuation to be reasonable to apply to all option grants in 2011 as “based on our progress at the time” is vague.
16. You disclose that additional valuations were performed by an independent valuation firm as of December 5, 2012. Please provide similar disclosure related to this valuation as provided for your December 2010 and September 2012 valuations, taking into consideration the above comments.

IPO price versus last valuation, page 73

17. Once you can reasonably estimate the IPO price, qualitatively and quantitatively discuss each significant factor contributing to the difference between the last valuation and the estimated IPO price. We will further evaluate your ordinary share valuation when your IPO price has been set. With regard to the last sentence:
- disclose the date when results of the first placebo-controlled clinical study of drisapersen became known; and
  - explain to us why conversion of preferred shares into ordinary shares affects the fair value of the ordinary shares.

Business

Our research and development pipeline—Drisapersen, page 84

18. You state that the frequencies reported in various international DMD mutation databases support your conclusion that the skipping of exon 51 could affect dystrophin expression in approximately 13% of DMD patients. You make similar statements elsewhere regarding the potential population for certain of your other product candidates and include these population estimates in the table on page 78. Please cite the databases you reference, and clarify whether the frequencies reported are consistent or whether your figures are based on, for example, an average of the data.

Collaboration, license and funding arrangements—GlaxoSmithKline, page 91

19. You disclose that you are eligible to receive up to €524 million in total milestones and other payments upon successful compound development and commercialization and that milestones generally relate to development and regulatory achievements, of which a portion of the milestone payments relates to drisapersen. Please revise your disclosure
- to clarify whether the €524 million includes potential payments related to compounds to which GSK has not yet exercised its option;
  - to disaggregate the €524 million separately for milestones and other payments;
  - to further disaggregate the milestone payments to be received into meaningful categories such as development, regulatory, and/or commercial milestones by compound, and to disclose the nature of the underlying events that trigger the milestone payments;
  - to further disaggregate the other payments to be received by compound, and to disclose the nature of the underlying events that trigger the other payments;
  - to disclose the amount of the option exercise payments;
  - to specify the amount of royalties payable expressed as a percentage or range within 10% (i.e. teens, twenties, etc.); and
  - to describe the duration and termination provisions of the agreement.

In addition, please file a copy of this agreement as an exhibit pursuant to Item 601 of Regulation S-K.

Collaboration, license and funding arrangements—Leiden University Medical Center, page 92

20. You disclose that the aggregate milestone payments you are obligated to make to LUMC range from approximately €1.4 million, if you achieve such milestones in relation to an initial orphan drug indication, to approximately €5.5 million, if you achieve such milestones in relation to a non-orphan drug indication. You also disclose that you may be obligated to pay LUMC additional milestone payments in relation to products approved for additional orphan drug indications. Please revise your disclosure:
- to clarify whether the €5.5 million aggregate payments includes the €1.4 million of payments for the initial orphan drug indication or only the payments for the non-orphan drug indication;
  - to quantify the additional milestone payments for the additional orphan drug indications; and
  - to disclose your termination right for convenience upon six months' notice.

Intellectual property, page 96

21. You state on page 79 that you have 15 U.S. patent applications relating to you technology and product candidates. Please reconcile this statement with your statement that you have 11 U.S. patent applications relating to your DMD program and 5 U.S. patent applications relating to your other programs.

22. Please revise your disclosure to clarify whether the families of patents licensed from LUMC and described in the second full paragraph on page 96 are in addition to the patents and patent applications described in the preceding paragraph.
23. Please expand your discussion to disclose the expiration dates of your material patents other than those directed to drisapersen.

Related party transactions, page 127

24. Please clarify the board members nominated by each of the shareholders identified under “Board composition” on page 127.

Note 10. Derivative financial instruments, page F-29

25. You disclose that the holders of Class A and Class B preferred shares have anti-dilution protections and the fair value of the anti-dilution preference is determined and separately recorded as an embedded derivative. You also state that the anti-dilution preference is measured at fair value through profit and loss and valued at nil as of 12/31/12. Please provide us your analysis supporting your accounting and reference for us the authoritative literature you rely upon.

Note 18. Borrowings  
Other Loans, page F-40

26. Please disclose and quantify each of the “certain pre-defined milestones” that trigger repayment of each of your loans.
27. Disclose when the loan from Agentschap was received. Also, disclose in euros the amount received from Charley’s Fund. Reconcile for us the amounts received in 2012 disclosed in Note 18 to the €3,853 presented on the statement of cash flows for 2012.

Item 8 Exhibits, page II-2

28. Please file a copy of each of the following agreements as an exhibit pursuant to Item 601 of Regulation S-K:
  - your 2012 loan agreement with AFM;
  - your employment agreements with Giles Campion, Luc Dochez, Berndt Modig, and Hans Schikan;
  - the 2004 Employee Stock Option Plan and form(s) of option agreement(s) entered into thereunder with any members of your supervisory or management board;
  - the 2006 Employee Stock Option Plan and form(s) of option agreement(s) entered into thereunder with any members of your supervisory or management board;

- the 2007 Employee Stock Option Plan and form(s) of option agreement(s) entered into thereunder with any members of your supervisory or management board;
- the 2010 Equity Incentive Plan and form(s) of option and restricted stock agreement(s) entered into thereunder with any members of your supervisory or management board; and
- the form of lock-up agreement with your directors, executive offices and other shareholders.

General

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 Sasha Parikh at (202) 551-3627 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Amy Reischauer at (202) 551-3793, Daniel Greenspan at (202) 551-3623, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler  
Assistant Director

cc: Via E-Mail  
Richard D. Truesdell, Jr.  
Davis Polk & Wardwell  
450 Lexington Avenue  
New York, NY 10017