

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

July 28, 2015

Via E-Mail
Kenneth T. Mills
Chief Executive Officer
REGENXBIO Inc.
9712 Medical Center Drive, Suite 100
Rockville, MD 20850

Re: REGENXBIO Inc.

Draft Registration Statement on Form S-1

Submitted July 1, 2015 CIK No. 0001590877

Dear Mr. Mills:

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.

Prospectus Summary

- 1. Please describe the meaning and significance of the following terms at their first use in this section:
 - adeno-associated virus (AAV);
 - in vivo;
 - lysosomes;
 - orphan drug product designation;
 - recessive genetic disease;
 - recombinant; and
 - vector.

- 2. We note the inclusion of various NAV Technology licensee product candidates in the table on page 2. The licensee product candidates are in a preliminary stage of development and your involvement in such development is limited. In addition, the prospectus summary provides insufficient context for an adequate understanding of the license agreements. Please delete the licensee product candidates table from the prospectus summary.
- 3. For your product candidates that are still in ongoing preclinical trials or research, please revise your pipeline table to shorten the blue bar so that it does not extend to the end of the stage column.
- 4. Please revise your disclosure in the prospectus summary to include a general description of the administration of your AAV gene therapy in patients. For example, please disclose how the therapy is delivered, whether the therapy is injected/infused into patients or whether the patient's own cells are harvested and isolated, if surgery is required and the intended injection or surgical sites in patients.
- 5. Please revise your disclosure in the Prospectus Summary to provide the number of individuals who have each of the illnesses for which your product candidates are intended to treat.

Risk Factors

Because we are developing product candidates for the treatment of diseases, page 13

6. Please define the term "clinically meaningful" when the term first appears in the prospectus.

Our future success depends on our ability to retain key employees..., page 38

7. Please expand your risk factor disclosure to identify your key executive officers and other key employees by name and job title.

Product liability lawsuits against us could cause us to incur substantial liabilities..., page 42

8. Please expand your disclosure in this risk factor to quantify the amount of product liability insurance you carry. Also, for any other type of insurance coverage discussed in other risk factors, please quantify the amount of insurance you carry.

We will incur increased costs as a result of operating as a public company..., page 58

9. Please include an estimate of the additional legal, accounting and other costs you expect to incur as a public company in your prospectus. Also provide a separate estimate for costs associated with the remediation of material weakness identified in your internal control over financial reporting.

Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expense, page 71

10. Please expand your disclosure to include the total costs incurred during each period presented for each project or product candidate separately to provide more transparency as to the type of expenses incurred. If you cannot disaggregate the amount of expense by product candidate, disaggregate the amount by nature of expenses or in some other manner.

<u>Critical Accounting Policies and Significant Judgements and Estimates Stock-Based Compensation</u>
Common Stock Valuation Methodology, page 77

11. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

Broad and Novel Tissue Selectivity, page 102

12. Please revise to briefly disclose why retinal pigment epithelium and the photoreceptor layer are critical to most inherited retinal degenerations.

Planned Clinical Development of RGX-501, page 107

13. We note your communications with the FDA and NIH. Please revise your disclosure in your business section to discuss the dates and substance of any material communications you have had with each of the FDA and NIH, and any material actions that you have taken or plan to take in response to the these communications.

<u>License Agreements and Commercial Licenses</u> <u>The Trustees of the University of Pennsylvania, page 113</u>

14. Please revise your disclosure on page 113 regarding your license agreement with The Trustees of the University of Pennsylvania to provide the aggregate amounts paid to date under the agreement and the aggregate future potential milestones to be paid under the agreement, if any.

GlaxoSmithKline LLC, page 115

15. We note that under the GlaxoSmithKline LLC (GSK) license agreement described on page 115, exclusivity of such license grant is subject to ``certain rights'' retained by GSK and Penn or retained by GSK for the benefit of itself and other third parties. Please expand your disclosure to describe these rights.

16. Please revise your disclosure on page 115 regarding your license agreement with GSK to provide the aggregate milestone payments made to date under the agreement. If no such payments have been made, please disclose this in the registration statement.

Commercial Licenses to NAV Technology Licensees, page 115

17. For each commercial NAV technology license described, please revise to disclose the total amount of fees you have received to date under each license agreement and separately state the aggregate milestone payments received to date for each such license you granted, if applicable.

Other Licenses, page 122

- 18. Please revise your disclosure on page 122 regarding the license agreements described in this section to provide:
 - the aggregate amounts paid to date under the agreement with the Regents of the University of Minnesota; and
 - the royalty rates, the aggregate potential milestones to be paid and the aggregate amounts paid to date under the agreement with ARIAD Pharmaceuticals, Inc.

If no such payments have been made, please disclose this in the registration statement. Alternatively, explain why you are not required to provide this information.

AAV Vector Expertise, page 123

19. We note that you have two agreements with WuXi AppTec, Inc. regarding the manufacture of supplies of your product candidates. We also note your disclosure on page 31 that it would be difficult to find a suitable replacement should your agreement with WuXi be terminated. Please expand your disclosure to provide the material terms of the agreements, including the parties' rights and obligations under the agreement, the duration of the agreement, termination provisions and any payment provisions.

Proprietary Methods, page 124

20. Please revise to clarify the extent to which the proprietary technology underlying your NAV technology platform and manufacturing systems were developed in-house as compared to being licensed from Penn or developed through your SRAs with Penn.

Principal Stockholders, page 166

21. Please update your beneficial ownership table so that it is as of the most recent practicable date.

Choice of Forum, page 174

22. We note your disclosure regarding provisions of your amended and restated certificate of incorporation and amended and restated bylaws stating that the Delaware Court of Chancery shall be the sole and exclusive forum for any stockholder bringing specified actions. Please add a risk factor describing the attendant risks to investors. For example, please highlight that such a provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with directors, officers or other employees, and may discourage lawsuits with respect to such claims.

<u>Statement of Convertible Preferred Stock and Preferred Units, and Stockholders' and Members'</u> Equity (Deficit), page F-5

23. Tell us how you determined the amount of accretion (decretion) of convertible preferred stock for the three months ended March 31, 2015 of \$(2.28) million and \$1.338 million and the basis for your determination. Explain why the carrying amount of the preferred is equal to the redemption amount at March 31, 2015 when it is not redeemable until December 31, 2019.

Notes to Financial Statements

8. Stock-based Compensation, page F-33

24. Provide us your computation of expected volatility of 64% for stock options granted to employees. Include the names of the similar companies you used, the volatilities of each and why you selected each company as being similar to you.

11. Related Party Transactions, page F-40

25. Please explain to us your basis for estimating the fair value of shares received from Dimension Therapeutics, Inc. in the October 2013 license agreement. Also provide us your analysis supporting immediate revenue recognition of \$2.7 million and general and administrative expense of \$2.7 million. Include references to supporting authoritative literature. Similarly, tell us why immediate recognition of two up-front fees in the three months ended March 31, 2014 is appropriate.

Other Comments

- 26. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 27. Please confirm that the graphics included in your registration statement are the only graphic, visual, or photographic information 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.

- 28. 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.
- 29. Your exhibit index indicates that you have submitted a confidential treatment request with respect to portions of certain of your exhibits. Please note that our comments on your request for confidential treatment will be provided under separate cover.

You may contact Rolf Sundwall at (202) 551-3105 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Preston Brewer at (202) 551-3969, John Krug at (202) 551-3862 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>
Jay K. Hachigian, Esq.
Keith J. Scherer, Esq.
Gunderson Dettmer LLP