



DIVISION OF  
CORPORATION FINANCE

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

December 10, 2014

Via E-mail

Ron Babecoff  
Chief Executive Officer  
BiondVax Pharmaceuticals Ltd.  
14 Einstein Street  
Nes Ziona, Israel 74036

**Re: BiondVax Pharmaceuticals Ltd.  
Draft Registration Statement on Form F-1  
Submitted November 13, 2014  
CIK No. 0001611747**

Dear Dr. Babecoff:

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.

Form F-1

1. We note the following press releases which allude to a proposed public offering of your securities:
  - the press release labeled “Universal flu vaccine co BiondVax Pharmaceuticals mulls NY IPO” published by BioSpace and dated November 24, 2014 (see [http://www.biospace.com/news\\_story.aspx?StoryID=355871](http://www.biospace.com/news_story.aspx?StoryID=355871)); and
  - the press release labeled “Universal flu vaccine co BiondVax mulls NY IPO; BiondVax is exploring two options - either a conventional offering or listing American Depositary Receipts” published by Israel’s Business Arena and dated November 23, 2014 (see <http://www.globes.co.il/en/article-universal-flu-vaccine-developer-biondvax-mulls-ny-ipo-1000988429>).

Please provide us with your legal analysis explaining why these communications are permissible in light of the requirements of the Securities Act of 1933 regarding pre-filing communications. In addition, please advise us of any steps that you have taken to prevent the further distribution or publication of similar communications going forward. For guidance, please refer to SEC Release No. 33-8591.

About This Prospectus, page i

2. Please note that it is not appropriate to directly or indirectly disclaim liability for information in the registration statement. Please remove the following statements:
  - “However, this information may prove to be inaccurate because of the method by which some of the data for the estimates was obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. As a result, the market and industry data and forecasts included in this prospectus, and estimates and beliefs based on that data, may not be reliable.”
  - “However, we have not independently ascertained the accuracy, completeness or reliability of the underlying economic assumptions relied upon therein.”

Prospectus Summary, page 1

3. We note on pages 1, 52, and 63 that you own or license four families of patents filed in a large number of jurisdictions, the latest of which is expected to be in force until 2035. We also note on page 83 that your patents are expected to expire between 2019 and 2031 and that patents issued from applications that will be filed from the additional provisional application would be due to expire in 2035. Please expand your disclosure on pages 1, 52, and 63 to clarify when your current material patents are expected to expire by jurisdiction and that you have not yet filed those patents that would be expected to expire in 2035.
4. We note on pages 2 and 63 that the FDA reviewed and commented on your IND submitted in June 2013. Please expand your disclosure to include a summary of any material communications from the FDA.
5. Please define “Drug Master File” the first time this term is used.
6. We note on page 2 that you experienced difficulties in obtaining H5N1 avian flu vaccine. Please expand your disclosure to discuss the reason that this difficulty prevented you from completing the IND application. Additionally, please expand your disclosure to explain when and how you acquired access to the H5N1 avian flu vaccine.

7. We note on page 2 that you plan to seek to establish collaborations with large multinational pharmaceutical companies and/or national health authorities to conduct Phase 3 clinical trials of M-001. We also note throughout your prospectus that you plan to conduct Phase 3 clinical trials in the U.S. For example, on page 5 you state that you plan to “conduct Phase 3 clinical trials” and “perform advanced trials (including Phase 3 clinical trials).” Please revise your disclosure throughout your prospectus to clarify the extent to which you intend to rely on a collaborator to conduct or aid in the completion of certain Phase 3 clinical trials.
8. We note on page 4 that you expect your future sales not to be limited to the influenza seasons. Please expand your disclosure to discuss the potential seasonality for sales of M-001 as a universal seasonal primer for the elderly or as a universal pandemic primer indication.
9. We note that in several places in your prospectus in which you characterize the drug as “safe” or “effective.” For example, on pages 4 and 66, you refer to an “effective dose;” on pages 5 and 67, you state that the trial results “show that M-001 was safe across all treatment groups;” and on page 69 you state that preclinical trials have “demonstrated that M-001 provides an effective flue protection.” Because regulatory approval of M-001 is dependent on the agency making a determination (according to criteria specified in law and agency regulations) that a drug is safe and effective, it is premature for you to describe M-001, or any of the dosages administered, as safe or effective. Accordingly, please delete this wording throughout your prospectus, as applicable.

#### Risk Factors

##### We have only conducted Phase 1 and Phase 2 clinical trials, page 18

10. We note on page 18 that you state that you have never submitted an IND application to conduct a Phase 3 clinical trial in the U.S. Please expand your disclosure to identify and discuss your IND application submitted in June 2013.

##### International patent protection is particularly uncertain, page 29

11. We note that you have licensed or own patents that were granted in China (see p. 83). Accordingly, identify China as one of those foreign countries that may not protect your intellectual property rights to the same extent as the United States.

##### Our U.S. shareholders may suffer adverse tax consequences, page 35

12. Please explain why you are unable to determine if you are a PFIC for any year. Additionally, please briefly explain that U.S. shareholders may be required to file additional forms with the IRS.

We are a “foreign private issuer” and have disclosure obligations that are different from those of U.S. domestic reporting companies, page 36

13. The Israeli parliament recently adopted a rule that requires an Israeli public company that is listed overseas, such as in the United States, to disclose annually the compensation of its top five executive officers on an individual basis regardless of whether the company is listed in Israel. Please revise this risk factor to reflect this new rule. Further clarify how, despite this new rule, as a foreign private issuer, you will not be required to provide in your Exchange Act reports “individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies.”

Use of Proceeds, page 44

14. We note that subject to FDA approval to commence Phase 3 clinical trials, you plan to allocate approximately \$2 million for the manufacturing of clinical grade Phase 3 vaccine batches and commercial batches over a period of 3 years. We also note on page 64 that you may seek to finance Phase 3 clinical trials of M-001 for some indications with your own resources, if sufficient. Please clarify your plans to allocate any of the proceeds from this offering to certain Phase 3 trials by indication, and state whether such allocation is expected to be sufficient to complete the respective Phase 3 trial.

Capitalization, page 46

15. Please revise the presentation of this table to remove cash and cash equivalents, or alternatively clearly indicate that it is not a component of capitalization by adding an underline or double underline under the amounts as well as a blank line.

Business, page 63

16. We note on page 64 that you intend to seek to establish collaborations with large multinational pharmaceutical companies and/or national health authorities to conduct Phase 3 clinical trials of M-001. Please expand your disclosure to discuss when you plan to seek out a collaborator and your reliance on finding a collaborator for purposes of developing M-001.
17. We note that you completed your BVX-005 Phase 2 trial in February 2012. Please expand your disclosure to discuss your operations and principal activities for the prior two fiscal years ending in December 31, 2013 and the interim period.

Current Outlook, page 57

18. Please file the your OCS grants as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

Universal Standalone Indication, page 67

19. We note your statement that “these rates in the general and elderly populations will increase considerably, as doctors and patients become aware of the increased effectiveness of [y]our product.” Please revise this statement to consider the risks of commercialization and competition, as well as expand on the risk that doctors may not find your product sufficiently effective, even if the FDA approves your product.

Other Product Candidates to be Developed, page 69

20. We note a recent press release from MonoSol RX stating that you have entered into a partnership. See [http://www.monosolrx.com/content/media/releases/news\\_110712.htm](http://www.monosolrx.com/content/media/releases/news_110712.htm). Please revise your disclosure to clarify whether you have entered into any such collaboration agreement with MonoSol RX. Additionally, if material, please expand your disclosure to discuss the material terms of this agreement, including whether the agreement is exclusive, material payment obligations, the duration, and material termination provisions. Please also file the agreement as an exhibit.

Safety and Efficacy Preclinical Trials, page 69

21. Please expand your disclosure to clarify that the safety and efficacy of your product for human patients cannot be determined based on preclinical trials.

Results of our Clinical Trials, page 71

22. We note on page 1 that for your Phase 1/2 clinical trials you tested for both safety of M-001 as your primary endpoint and immunogenicity of M-001 as your secondary endpoint. We also note on page 71 and 72 that clinical trials BVX-002, BVX-003, and BVX-004 were aimed at “assessing the safety and tolerability of M-001.” Please revise your disclosure to clarify whether these clinical trials tested for immunogenicity or any other primary or secondary endpoints. Additionally, if your clinical trials tested for any additional endpoints, please expand your disclosure to discuss the material results of your studies.

BVX-005, page 72

23. Please include a description of the goals of the trial, the primary endpoints and any secondary endpoints, and any additional results obtained. Additionally, please expand your disclosure to discuss the significance of an increase in the proportions of interferon gamma secreting cells and influenza antigens. Also, please define influenza antigens the first time this term is used.

Future Phase 3 Clinical Trials, page 73

24. We note that you may initiate Phase 3 trials for some or all of your indications. Please expand your disclosure to state how you plan to prioritize which Phase 3 trials you will perform or the order that you will perform them.

Grant from the European Union, page 77

25. We note your statement on page 77 that you have entered into a framework agreement which defines the Consortium rules of conduct as well as conditions under which you are receiving €0.5 million. Please expand your summary to disclose the material rules and conditions of the framework agreement.

Intellectual Property, page 83

26. We note that your patents are expected to expire between 2019 and 2031. Please expand your disclosure to clarify when your patents are expected to expire in each of your material jurisdictions.
27. We note that you have licensed two families of patents and also that you have licensed three families of patents from Yeda. Please revise your disclosure to clarify the number of families of patents that you have licensed.

Management

Compensation, page 92

28. Disclose the total amount set aside or accrued by you to provide pension, retirement or other similar benefits for your executive officers and directors during the most recently completed fiscal year. See Item 6.B.2. of Form 20-F.

Board Practices, page 97

29. Please expand your disclosure to provide the details of your directors' service contracts with the company that provide for benefits upon termination of employment or an appropriate negative statement.

Shares Eligible for Future Sale

Rule 144, page 127

30. Please state the number of your ordinary shares that will be restricted securities under Rule 144 upon completion of this offering.

Taxation

U.S. Federal Income Tax Consequences, page 130

31. Please delete your disclaimer that the tax “summary is for general purposes only and does not constitute tax advice” as it improperly implies that an investor may not rely on the U.S. tax information disclosed in the registration statement.

Where You Can Find More Information, page 145

32. We note your disclosure that you have filed Hebrew language periodic and immediate reports with the TASE and the ISA, as required under the Israel Securities Law. Further disclose that, as an Exchange Act reporting foreign private issuer, you will be required to furnish to the SEC under Form 6-K English translations or, in certain instances, English summaries of your material home country documents. See Exchange Act Rule 12b-12(d).

Notes to Financial Statements

33. It appears that there are some inconsistencies regarding the numerical values indicated in the footnotes as being “in thousands, except per share data”. For instance, on page F-38 in Note 14d you indicate that you entered into an agreement for the sale of up to \$7,000,000 of your ordinary shares. In this regard, it would appear that the agreement was for \$7 billion. Please revise the notes to financial statements for consistency.

Note 14. Equity, page F-37

34. It appears that your series 3 and series 5 options have variable exercise terms. Please tell us your accounting basis for classifying these options as equity. Reference for us the authoritative guidance you relied upon to support your accounting and classification.

Exhibit Index

35. Please file the amendment to the employment agreements between the company and Mr. Uri Ben Or as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.
36. Please file the employment agreement between the company and each member of the Scientific Advisory Team as an exhibit.

General

37. Please file all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.

Ron Babecoff  
BiondVax Pharmaceuticals Ltd.  
December 10, 2014  
Page 8

38. 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.
39. 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.

You may contact Sasha Parikh at (202) 551-3627 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786, John Krug at (202) 551-3862, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler  
Assistant Director

cc: Ilan Gerzi, Adv.  
Tammy Zoppo, Esq.  
Pearl Cohen Zedek Latzer Baratz  
One Azrieli Center,  
Round Tower, 18th Floor  
Tel-Aviv 6702101, Israel