



DIVISION OF  
CORPORATION FINANCE

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

March 12, 2020

John C. Jacobs  
Chief Executive Officer  
Harmony Biosciences Holdings, Inc.  
630 W. Germantown Pike, Suite 215  
Plymouth Meeting, PA 19462

**Re: Harmony Biosciences Holdings, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted February 14, 2020**  
**CIK No. 0001802665**

Dear Mr. Jacobs:

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.

Draft Registration Statement on Form S-1

Overview, page 1

1. Briefly expand the disclosure regarding the six approved medications for the treatment of narcolepsy by including the reasons these medications are prescribed, to balance the negative side effects currently discussed.
2. Please expand your discussion of the company's strategy of expanding the label for WAKIX to include cataplexy and pediatric applications to explain how each of these new goals relate to the current offer. If you will not be able to complete the related trials and address the related development costs with the proceeds of the offer, please disclose that these goals will not be achievable without additional funding.

Overview of the Development Pipeline, page 4

3. We note the inclusion of four proposed label expansions in the table on page 4. Please expand the table and your disclosure to provide more information about the company's progress with respect to pre-clinical trials for these label expansions. If you have undertaken IND enabling studies for any of the treatments listed in the table, please describe these studies in the disclosure. Alternatively, please state in the disclosure surrounding the table where you are in the IND process.
4. Please balance the pipeline table disclosure by stating the approximate number of patients worldwide who could benefit from each of the therapies in the table or otherwise clarify your estimate of the potential market size for each therapy.

Risk Factors, page 14

5. We note that there are references to foreign regulators and foreign markets throughout the Risk Factors and other sections of your prospectus. Please revise to explain what non-US markets, if any, you plan to enter, and what steps you have taken to attain the necessary regulatory and patent approvals.
6. We note your disclosure on page 168 that your exclusive forum provision does not apply to actions arising under the Securities Act or the Exchange Act. Please ensure that the exclusive forum provision in the bylaws (as effective on the closing of the offering) states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act.

Use of Proceeds, page 72

7. We note the use of proceeds to fund the clinical development of additional indications for pitolisant in PWS, DM1 and pediatric narcolepsy. Please revise to specify how far the proceeds of the offering will take the company into the clinical development of these potential additional indications. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Instruction 3 of Item 504 of Regulation S-K.

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

Cost of Product Sales, page 81

8. Please revise to address the following:
  - Disclose the amount of estimated historical cost of the inventory build-up prior to your regulatory approval that had been expensed as research and development expenses for each period presented.
  - Disclose the effect zero cost inventory had on your historical results of operations.
  - Disclose the expected effect on future results of operations and the assumptions made

- in this regards.
- Disclose what the shelf life of your inventory is and your consideration of whether or not any additional inventory will be determined to be obsolete in future periods.
- Disclose what you estimate your gross margin percentage will be after the zero cost inventories are sold.

Liquidity and Capital Resources, page 86

9. You disclose that the Credit Agreement with OrbiMed requires compliance with certain financial covenants, including minimum net revenue thresholds and cash balance requirements, and financial reporting requirements. Please amend your filing to disclose whether you were in compliance with your covenants for each period presented. If not, please discuss any consequences that you may be subject to as a result of default, absent a waiver.

Stock-Based Compensation, page 93

10. Please revise to disclose the extent to which any stock-based compensation has been awarded during 2019 and through the date of your filing, and provide the fair valuations of each award in the *Common Stock Valuations* section that follows on page 94. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Competition, page 122

11. Expand your discussion of competition to discuss the principal methods of competition, including price. Identify the positive and negative factors affecting Harmony's competitive position, to the extent they are known. Refer to Regulation S-K, Item 101(b)(2)(x).

General

12. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.
13. 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.

John C. Jacobs  
Harmony Biosciences Holdings, Inc.  
March 12, 2020  
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You may contact Tracey McKoy at 202-551-3772 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Julia Griffith at 202-551-3267 or Susan Block at 202-551-3210 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences