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

DIVISION OF
CORPORATION FINANCE

March 13, 2018

Ashleigh Palmer
President & Chief Executive Officer
Provention Bio, Inc.
110 Old Driftway Lane
Lebanon, New Jersey 08833

Re: Provention Bio, Inc.
Draft Registration Statement on Form S-1
Submitted February 12, 2018
CIK No. 0001695357

Dear Mr. Palmer:

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.

DRS on Form S-1 Submitted February 12, 2018

Prospectus Summary, page 4

1. Throughout your summary and registration statement you reference clinical trials that have been performed as de-risked with respect to safety and proof of mechanism or proof of concept. Please clarify if the trails performed by the licensor were preclinical, Phase I, II or III. Additionally, safety and efficacy are determinations within the exclusive authority of the FDA or equivalent foreign regulators. It is not appropriate to indicate that the trials demonstrated safety.

2. Please explain the term "translational" with respect to "translational and early stage

development," "translational-stage clinical trials" and "translational medicine."

3. The term "de-risked" appears to imply that your access to data from previous trials performed by other parties has eliminated your risk related to your product candidates. If accurate, you may disclose that administration of a product candidate was well tolerated or resulted in no serious adverse events. However, it is not appropriate to imply that the risk related to safety and/or efficacy has been eliminated. Please review the registration statement to eliminate the use of the term "de-risked." If you choose to say that the product candidate was well tolerated in previous clinical trials or that there were no serious adverse events, please disclose how many clinical trial participants received the product candidate, the length of the trials and dosing amounts. Additionally, disclose any differences between your planned clinical trials and the ones previously performed and clarify that prior results are not necessarily predictive of the outcome of future trials.

4. We note your references to Vactech and Janssen with respect to your "substantial partnering experience." It appears from your agreements that you have purchased licenses from Vactech and Janssen, have agreed to engage in further activities to further the develop the products, will make milestone payments to the extent your efforts are demonstrate success and will pay royalties if you are successful in obtaining approval and commercializing the products. It does not appear that Vactech and Janssen are agreeing to participate in the further development of your product candidates by providing funding or significant services. Please explain why you believe the description of these parties as partners is appropriate or revise your registration statement to describe these arrangements as licensing arrangements, rather that partnerships.

<u>The proceeds from this offering will only fund our operations for a limited time..., page 13</u>

5. We note your disclosure that the proceeds from the offering and existing cash will be sufficient to fund your operations for approximately 24 amounts from the date of the offering. This information is inconsistent information on page 75 which states that the proceeds from the offering and your current cash are sufficient to meet your financial needs for at least 12 months from the date of the offering. Please revise your disclosure to ensure consistency throughout your registration statement.

<u>We are a biopharmaceutical company with a limited operating history, page 13</u>

6. Please explain the term "semi-virtual" and describe any risks related to this status. For example, any risks related to confidential materials, cyber security, etc.

<u>Even though we may apply for orphan drug designation for a product candidate..., page 13</u>

7. Please clarify whether you believe any of your current product candidates qualify for an orphan drug designation.

We depend entirely on the success of our product candidates, which have not yet demonstrated ef ficacy..., page 15

8. We note your statement that you have submitted your "clinical trial protocols and are awaiting approvals from the regulatory authorities...." Please summarize the nature and extent of your communications, if any, with the FDA regarding your product candidates and clinical trials, and specifically note whether you have an active IND for any of your upcoming clinical trails or have submitted an IND application.

Use of Proceeds, page 44

9. Please revise the discussion to separately identify the amounts you intend to allocate to each of your product candidates. and identify the stage of development you expect to achieve with the proceeds of the offering for each.. To the extent you expect to begin particular stage of development but do not expect to complete it, please indicate that you will need to raise additional funding to complete that stage of development. As the total proceeds will vary, depending on whether you sell the minimum or maximum number of shares indicates, please indicate the order of priority such uses and specifically address how your plans will change if you sell the minimum number of shares. Please refer to Instruction 1 to Item 504 of Regulation S-K.

Capitalization, page 46

10. Please provide a description of pro forma measures you plan to present on a minimum and maximum basis. In addition, state, if true, that the warrants will be accounted for as equity upon the IPO. If not, tell us why, in light of the fact that they will become exercisable for the purchase of common stock upon completion of the IPO.

11. You indicate that your table on page 46 presents cash and cash equivalents and capitalization on an actual, pro forma and pro forma as adjusted basis. The columns provided in your table, however, do not match this description. Please revise, as necessary.

Clinical Proof of Mechanism for PRV-6527, page 53

12. We note that three clinical trials were completed for PRV-6527. For each of the clinical trials discussed in this section, please disclose the date(s) of the trials and the location; patient information number of patients , duration of treatment,dosage information and the data providing evidence of proof of concept.

Clinical Safety of PRV-300, page 59

13. We note your statement in this section that "PRV-300 was generally safe...." Please remove statements suggesting that your product candidates are safe or effective as approval by the FDA and other regulatory agencies is dependent on such agencies making this determination.

Safety, Pharmacology and Proof of Mechanism for PRV-300, page 59

14. For the clinical trial(s) discussed in this section, please disclose the date(s) of the trials and the location; the number of patients, ; duration of treatment,dosage information.

Intellectual Property, page 68

15. For each of your material patents, please disclose (1) the specific product(s) to which such patents or patent applications relate; (2) whether the patents are owned or licensed from third parties, and if so, from whom; (3) the type of patent protection; (4) patent expiration dates and expected expiration dates for patent applications; and (5) the jurisdictions where patents are issued and patent applications are pending.

Vactech License, page 68

16. Please quantify the value of the two million shares you granted to Vactech at the time of grant.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies
Stock-Based Compensation, page 77

17. Please revise to disclose the following information. You may cross-reference to the extent that this, or other material information relevant to share-based compensation, is provided elsewhere in the preliminary prospectus.
    - The methods that management used to determine the fair value of the company's shares and the nature of the material assumptions involved;
    - The extent to which the estimates are considered highly complex and subjective; and
    - The estimates will not be necessary to determine the fair value of new awards once the underlying shares begin trading.

18. Once you have an estimated offering price or range, please provide us an analysis explaining the reasons for the differences between the recent valuations of your common stock leading up to the IPO 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.

General

19. 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.

20. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus.

Please note that we may have comments regarding this material.

You may contact Keira Nakada at 202-551-3659 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Suzanne Hayes at 202-551-3675 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Michael J. Lerner