

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

DIVISION OF CORPORATION FINANCE

September 28, 2018

David Young Chief Executive Officer Processa Pharmaceuticals, Inc. 7380 Coca Cola Drive, Suite 106 Hanover, MD 21076

> Re: Processa Pharmaceuticals, Inc. Amendment No. 1 to Registration Statement on Form S-1 Filed September 14, 2018 File No. 333-226428

Dear Dr. Young:

We have reviewed your amended 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our August 28, 2018 letter.

Amendment No. 1 to Registration Statement on Form S-1

Prospectus Summary, page 1

1. We acknowledge your response to prior comment 3. As noted in the prior comment, please also disclose when PTX was approved, the indication for which it was approved, and the fact that it was approved by the FDA.

Liquidity and Capital Resources, page 30

2. We note your disclosure that you anticipate needing an additional \$900,000 to continue planned operations through the fourth quarter of 2019. Please also disclose how long you

David Young Processa Pharmaceuticals, Inc. September 28, 2018 Page 2

expect your business operations to continue should you not be able to secure the additional \$900,000.

Description of Business, page 37

- 3. We acknowledge your revised disclosures in response to prior comment 15. As referenced in the prior comment, please further expand your revised disclosure to explain how you identified Radiation-Induced Fibrosis (RIF) in head and neck cancer patients as an indication for which PCS-499 may result in clinical efficacy.
- 4. We acknowledge your revised disclosure in response to prior comment 16 and that you acquired prior clinical data. As noted in the prior comment, please expand your disclosure to discuss specific trial results for your product candidate on which you intend to rely, including the duration of the trials, the number of subjects or patients in such trials, how the drug candidate was administered, who conducted the trials, the dosage used, any serious adverse events experienced, the primary and secondary endpoints and whether they were met.

Intellectual Property, page 38

5. Please further expand your revised disclosure to clarify the type of patent protection that you have for your issued patents (as compared to your patent applications), and identify all of the foreign jurisdictions in which you have patents or patent applications.

License Agreement with CoNCERT Pharmaceuticals, Inc., page 38

6. We note your response to prior comment 17. Please explain how the board observer rights expired as it does not appear that the amendment to the license agreement amended the provision.

Directors, Executive Officers, Promoters and Control Persons, page 43

 We refer to your disclosure regarding your newly appointed CFO. Please clarify whether Mr. Stanker's employment and experience at Grant Thornton is during the past five years. If not, please disclose his principal occupations during such period. Refer to Item 401(e)(1) of Regulation S-K.

Plan of Distribution, page 57

8. We acknowledge your response to prior comment 24. Please note that to the extent you expect to seek effectiveness of the registration statement prior to the filing of your agreement with PoC Capital in an upcoming Exchange Act report, please file this agreement as an exhibit to the registration statement.

David Young Processa Pharmaceuticals, Inc. September 28, 2018 Page 3

<u>Financial Statements</u> <u>Notes to Condensed Consolidated Financial Statements</u> <u>Note 2 - Intangible Asset, page F-38</u>

- 9. In your response to prior comment 25 you indicate that the reverse merger transaction between Processa Pharmaceuticals (formerly Heatwurx Inc.) and Promet Therapeutics was considered an IRC Section 351 tax-free contribution of assets by Promet solely for over 80% of the voting stock of Processa. You also indicate that included in the Contributed Assets were all rights, title and interest under a certain option and license agreement with CoNCERT Pharmaceuticals with respect to certain know-how, patent rights and compounds. Please address the following:
 - Revise your disclosures describing the reverse merger transaction to clarify that this transaction was treated as a tax-free contribution under IRC Section 351.
 - Confirm for us, if true, that as part of the reverse merger transaction in October 2017 you acquired an option to acquire a license from CoNCERT and that this option was subsequently exercised in March 2018. If so, explain how you determined that the subsequent exercise of this option should be considered as part of the initial Section 351 transaction. Provide us with any documentation to support your accounting treatment.
 - For impairment purposes, tell us how you determined that the carrying amount of this intangible asset (which includes the \$3m in capitalized costs) was recoverable as of June 30, 2018.

You may contact Andi Carpenter at 202-551-3645 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Ada Sarmento at 202-551-3798 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Neda Sharifi