

October 9, 2018

Via EDGAR

United States Securities and Exchange Commission
Division of Corporate Finance
Washington, D.C. 20549

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

Dear Sir or Madaam,

On behalf of Processa Pharmaceuticals, Inc. ("the Company" or "Processa"), we are responding to the comments of the staff of the Division of Corporate Finance of the United States Securities and Exchange Commission set forth in your letter to Dr. David Young, Processa's Chief Executive Officer, dated September 28, 2018. Your comments are reproduced below in bold, followed in each case by our response on behalf of the Company.

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

Prospectus Summary, page 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.**

Response

The Company has now added the requested information about PTX to the *Prospectus Summary* and the *Description of Business*.

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

Response

The Company has updated *Liquidity and Capital Resources* to reflect how long it expects its business operations to continue without additional funding.

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.

Response

The Company has revised *Description of Business* to address why PCS-499 may result in clinical efficiency for RIF.

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.

Response

The Company has revised *Description of Business* to expand upon the discussion of prior trials and the results that we are relying on.



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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.

Response

The Company has expanded its disclosure of patents in *Intellectual Property* to clarify the type of patent protection and better identify foreign jurisdictions where the Company has 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.

Response

Section 2.6 of the Option and License Agreement with CoNCERT Pharmaceuticals, Inc. dated October 4, 2017 provides that the right to a board observer seat expires when CoNCERT Pharmaceuticals, Inc.'s ownership interest in Promet first decreases below ten percent (10%) of Promet's outstanding voting stock. The March 19, 2018 amendment provides that the Company agrees to be bound by the terms to the same extent as Promet. CoNCERT Pharmaceuticals, Inc. now owns less than six percent (6%) of the Company's outstanding voting stock.

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

7. 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.

Response

Mr. Stanker's employment and experience at Grant Thornton did occur during the past five years. The Company has revised the description of Mr. Stanker to clarify this point.



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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.

Response

The pledge agreement with PoC Capital dated May 25, 2018 has now been filed as Exhibit 10.14 to the registration statement.

Financial Statements

Notes to Condensed Consolidated Financial Statements

Note 2 - Intangible Asset, page F-38

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.

Response

The Company has revised its disclosures in *Note 1 – Organizations and Summary of Significant Accounting Policies* on pages F-7 and F-33 to indicate the reverse merger transaction was accounted for as a tax-free contribution under Internal Revenue Code Section 351. The Company also revised *Note 5 – Income Taxes* on page F-42 to clarify that the contributed assets under the option and license agreement with CoNCERT Pharmaceuticals, Inc. for which voting shares of the Company were expressly contemplated to be issued as part and parcel with, and integrated into, the IRC Section 351 transaction because all the contributed assets, include the CoNCERT assets, were contemplated to be integral to each other and were considered to be an integrated undertaking as the primary target, purpose and reason for the overall transaction.

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The Company will include the revised disclosures in future filings.

- **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.**

Response

Pursuant to a request for confidential treatment, we have separately furnished the Company's Board Consent from September 2017 contemporaneously identifying the Section 351 transaction and the intended components of such transaction (the "2017 Consent"). While contemplated as part of the reverse merger, the option to acquire the license from CoNCERT was not transferred by Promet to Processa until the conditions to the option's exercise were satisfied and accepted by CoNCERT in March 2018.

As reflected in the 2017 Consent, the subsequent option exercise and release of stock to CoNCERT for the IP licensed in the transaction was known of, intended and considered so integral to the overall transaction and plan that the companies and their respective advisors included it in the transaction as part of the overall section 351 plan. Further, Section 351 provides that transactions need not be simultaneous to qualify, as long as a plan is in place. Reg. 1.351-1(a) states: "The phrase 'immediately after the exchange' does not necessarily require simultaneous exchanges by two or more persons, but comprehends a situation where the rights of the parties have been previously defined and the execution of the agreement proceeds with an expedition consistent with orderly procedure." The CoNCERT transaction was closed as soon as could be closed after the October 2017 transaction.

In March 2018, the Company estimated the fair value of the intangible asset as approximately \$11 million (consisting of \$8 million, based on the fair value of the 2,090,301 shares of common stock issued to CoNCERT (an unrelated party) and \$3 million due to recording an offsetting deferred tax liability). The Company also determined the expected life of the intangible asset to be 14 years.

- **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.**
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Response

ASC 360-10 provides that intangible assets with finite lives be reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. In the Company's evaluation of its intangible assets, it considers the term of the underlying asset life and the expected life of the related product line. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company would perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss in the statement of operations if the carrying value of the intangible asset exceeds its fair value. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to us or our competitors, new or better products entering the market, changes in market share or market pricing, changes in the economic lives of the assets, changes in the legal framework covering patents, rights or licenses, and other market changes which could have a negative effect on cash flows and which could result in an impairment.

The Company's development of PCS 499 is progressing in accordance with the Company's expectations, both from a technical and market perspective and are in accordance with the Company's budget. The Company did not identify any indication of impairment or any other significant adverse change related to the asset that would impact its recoverability. To the contrary, several positive events have recently occurred, including: on June 22, 2018, the U.S. Food and Drug Administration ("FDA") granted orphan-drug to the Company's leading clinical compound PCS-499 for treatment in Necrobiosis Lipoidica ("NL"); on August 29, 2018, the Company submitted to the FDA an Investigational New Drug (IND) application ("IND") for PCS-499 in NL with the plan to initiate a Phase 2 study in NL patients in 2018; and on October 2, 2018, the Company announced that the FDA granted the Company clearance to proceed with a Phase 2 clinical trial of PCS-499 in patients with NL under the recently submitted IND application.

If you should have any additional questions, please contact me at (904) 633-8913.

Sincerely,

/s/ Michael B. Kirwan

Michael B. Kirwan

MBK:arm

cc: Dr. David Young, Chief Executive Officer
John J. Wolfel, Esq.
Neda A. Sharifi, Ph.D., Esq.
