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CLIENT/MATTER NUMBER
100830-0118

September 14, 2018

Via EDGAR

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

Re: Processa Pharmaceuticals, Inc.
Registration Statement on Form S-1
Filed July 30, 2018
File No. 333-226428

Dear Ladies and Gentlemen,

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, Office of Healthcare and Insurance of the United States Securities and Exchange Commission set forth in your letter to Dr. David Young, Processa's Chief Executive Officer, dated August 28, 2018. Your comments are reproduced below in bold, followed in each case by our response on behalf of the Company.

Registration Statement on Form S-1

Cover Page

1. We note your disclosure that your common stock is quoted on the OTC Pink Market. Please revise here, and make corresponding changes elsewhere in the prospectus, to disclose a fixed price at which your shares will be sold until your shares are listed on a national securities exchange or quoted on the OTC Bulletin Board, OTCQB or OTCQX.

Response

The Company has revised the Prospectus cover page to reflect that the Company is making an application to the OTCQB and that Selling Stockholders will offer the shares of common stock at a fixed price until the Company's common stock is approved for trading on the OTCQB. The Company has made similar disclosures in the following sections of the prospectus: *Prospectus Summary*, *Risk Factors*, *Market Price of Our Common Stock and Related Stockholder Matters*, and *Plan of Distribution*.

Description of Business, page 1

2. Please provide more detail concerning the current stage of development of PCS-499 in this section such as whether PCS-499 is in the preclinical stage of development and whether you have conducted any clinical trials for PCS-499, filed any regulatory applications or had any pre-filing conferences with regulatory agencies.

Response

The Company has revised *Prospectus Summary - Description of Business* to provide more detail concerning the current stage of development of PCS-499 and the status of clinical trials, regulatory applications and pre-filing conferences with regulatory agencies.

Prospectus Summary, page 1

3. Please revise your disclosure to briefly explain in terms a lay reader would understand what you mean that your product candidate is an "analog of an active metabolite" of an already approved drug. Please also disclose the drug that is already approved, when it was approved, the indication for which it was approved, and the fact that it was approved by the FDA as disclosed elsewhere in the prospectus.

Response

The Company has expanded *Prospectus Summary - Description of Business* to explain, in terms a lay reader would understand, that PCS-499 has a structure similar to that of an approved drug, but differing from it with respect to a certain functional component of the molecule.

The Company has further disclosed the name and approved indications of the FDA approved analog.

4. We note your statement here, and elsewhere in the prospectus, that your lead product candidate compound has been shown to be "safe and tolerable" and "with a trend toward efficacy in diabetic nephropathy." Safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory authorities. Please revise your disclosure to remove all references to your product candidate as being effective, including preliminary indications of efficacy (whether for your planned indication or other indications). Please make similar revisions regarding your statements about your product candidate's safety. In the "Description of Business" section, you may present the objective results of trials.

Response

The Company has revised the Prospectus to remove all references to PCS-499 as being effective, including removal of references to preliminary indications of efficacy. Furthermore, the Company has made similar revisions regarding the safety of PCS-499.

Risk Factors, page 1

5. Please expand this section to disclose that you do not own any patents for your drug candidate and you are dependent on a license. Please also disclose in this section that you have not initiated any clinical trials and your independent registered public accounting firm's doubt about your ability to continue as a going concern.

Response

The Company has expanded *Prospectus Summary - Risk Factor* to disclose that (1) the Company does not own any patents for its drug candidates and is dependent on licenses; (2) the Company has not initiated any clinical trials and (3) the Company's independent registered public accounting firm has expressed doubt about the Company's ability to continue as a going concern.

Risk Factors, page 6

6. Please add a risk factor to discuss the fact that you do not currently have an audit or compensation committee and that only one of your directors is independent.

Response

The Company has included a new risk factor to discuss that the Company does not currently have an audit committee or compensation committee and that the Company does not currently have a majority of independent directors.

We depend on rights to certain pharmaceutical compounds that are or will be licensed to us, page 15

7. We note your disclosure in this risk factor that your drugs are in-licensed from other biotech or pharmaceutical companies and that you do not own the patents that underlie these licenses. Please specify the product candidates that you are referring to as well as the patents and the biotech or pharmaceutical companies from whom you have licensed such patents.

Response

The Company has revised the Risk Factors relating to its intellectual property rights to specify the licensed product candidates as well as the patents and biotech or pharmaceutical companies from whom the patents have been licensed.

There may be limitations on the effectiveness of our internal controls, page 19

8. We note your disclosure that you experienced a cybersecurity breach that resulted in a fraud loss where the probability of recovery of the loss is remote. Please disclose when the breach occurred and quantify the loss in this risk factor.

Response

The Company has revised its disclosure to include the date and dollar value of the loss suffered by the Company as a result of the cybersecurity breach.

Our principal stockholders have significant influence over us, . . ., page 21

9. Please expand this risk factor to also discuss the combined ownership of your 5% stockholders in addition to your executive officers, directors, and their affiliates.

Response

The Company has expanded this risk factor to discuss the combined ownership of the Company's 5% stockholders in addition to its executive officers, directors, and their affiliates.

Liquidity and Capital Resources, page 30

10. Please disclose how long you expect your business operations to continue given your current amount of cash and funds. If you expect that your business operations cannot continue given your current amount of cash and funds, please disclose the amount of additional financing necessary to continue operations.

Response

The Company has expanded *Liquidity and Capital Resources* to include the expected continuation of business operations given the Company's current and projected cash flow and funds.

Description of Business, page 37

11. We note your disclosure on page 37 regarding your team's prior experience developing drug products. Please revise your disclosure to provide balancing language that the prior experience of your team is not an indication of a similar result with respect to Processa.

Response

The Company has added balancing language to such disclosure stating that the prior experience of the Company's team is not a guarantee of a similar result in the future.

12. We refer to your statement that your business strategy is to identify drugs that can be "quickly" developed within "2-4 years." Please tell us why you believe this time frame is realistic given the lengthy and uncertain process of seeking regulatory approval.

Response

The Company has expanded the description of its business model to explain the justification for identification of drugs that can be quickly developed within 2-4 years.

13. We note your statement that part of your business strategy is to identify drugs that have potential efficacy in patients with an unmet medical need, even if the evidence is "anecdotal." Please revise this disclosure to explain how you would consider anecdotal information to serve as clinical evidence.

Response

The Company has revised *Description of Business* to explain utilization of published case studies or clinical studies to serve as clinical evidence.

14. Please quantify your funding obligations under your CRO agreement with Integrium, LLC to conduct your planned Phase 2 study for PCS-499 in the treatment of NL. Please also disclose whether the $1.8 million that will be paid directly to Integrium by the investor will be sufficient to complete the planned Phase 2 clinical trial.

Response

The Company has revised *Description of Business* to include an explanation of the terms of the Company's CRO agreement with Integrium, including explanation of funding obligations and sufficiency of funds to complete the planned Phase 2 clinical trials.

15. Expand your disclosure to explain how you identified Necrobiosis Lipoidica (NL) and Radiation-Induced Fibrosis (RIF) in head and neck cancer patients as indications for which PCS-499 may result in clinical efficacy.

Response

The Company has revised *Description of Business* to explain the process of identification of NL and RIF in head and neck cancer patients as indications for which PCS-499 may result in clinical efficacy.

16. We note your disclosure that you intend to pursue a Phase 2 clinical trial for PCS-499. Please disclose how you will proceed to a Phase 2 trial given that it appears that you have not conducted any Phase 1 clinical trials and disclose the regulatory pathway that you intend to pursue. Please expand your disclosure to discuss specific trial results for your product candidate on which you intend to rely, including the duration of the trial, 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 revised *Description of Business* to further explain that due to previous preclinical studies, Phase 1 and Phase 2 clinical work completed in support of PCS-499, the Company anticipates moving the product into Phase 2 studies for the new indications.

Asset Acquisition, page 38

17. Please revise this section to discuss the material terms of your CoNCERT agreement, including the nature and scope of the intellectual property transferred, each parties' duties and obligations, the term of the agreement, the royalty term, the royalty rates, the termination provisions and any potential milestone payments. We also note the discussion on page F-26 concerning CoNCERT's right to have one Board observer attend the Promet's Board meetings. If CoNCERT still has that right with respect to Processa's Board meetings, please discuss it here.

Response

The Company has revised *Description of Business* to include a new sub-section titled *"- License Agreement with CoNCERT Pharmaceuticals, Inc."* that describes the material terms of the Company's license agreement with CoNCERT Pharmaceuticals, Inc. Please note that CoNCERT Pharmaceuticals, Inc. does not have, and never has had, any board observer rights with the Company as such rights expired upon the assignment of the license agreement from Promet to the Company. The reference to board observer rights has been removed from the notes to the financial statements.

Intellectual Property, page 38

18. Expand your disclosure to discuss the patents you have licensed relating to your product candidate, including the jurisdiction, the type of patent protection (e.g., composition of matter, use, or process), and the patent expiration dates.

Response

The Company has expanded its intellectual property disclosure to include the quantity, jurisdiction, type and expiration dates of its licensed patents.

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

19. Please revise to explain how Dr. Young helped Questcor transition from being nearly bankrupt to having a valuation of over $5 billion in his role as an independent director or remove this statement from his biography.

Response

The Company has revised Dr. Young's biography to explain Dr. Young's role as an independent director and subsequently as the Chief Scientific Officer of Questcor in transitioning Questcor from nearly a bankrupt company to ultimately the sale of the company for over $5 billion.

Corporate Governance, page 45

20. We note your statement here that Mr. Thompson is independent as defined by NASDAQ Rule 5605, and your statement in your Annual Report on Form 10-K filed on April 2, 2018, as amended, that there were no independent directors on your board under this rule, which would include Mr. Thompson. Please explain what factors led to this change.

Response

The Company's Board has reviewed the Nasdaq independence rules with both of its non-employee directors, Justin Yorke and Virgil Thompson, and has concluded that each of such directors have always satisfied the independence requirements for service on the Company's Board of Directors and for service on any future audit committee. Accordingly, the Company has revised the *Corporate Governance* section to disclose that such directors are independent. The Company will correct the independence determinations set forth in its Form 10-K filed on April 2, 2018 in future filings to indicate that such directors are independent and have been independent since the commencement of their respective service with the Company as directors.

Security Ownership of Certain Beneficial Owners and Management, page 49

21. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by Promet Therapeutics, LLC, CorLyst, LLC and CoNCERT Pharmaceuticals, Inc. Please also confirm whether Dr. Young has voting and investment control of the shares held by the Young-Plaisance Revoc Trust.

Response

The Company has included additional footnotes to (1) identify the natural person who has voting and investment control of the shares held by Promet Therapeutics, LLC, CorLyst, LLC and (2) to confirm Dr. Young's voting and investment control of the shares held by the Young-Plaisance Revoc Trust. Please note that the Company is not aware of any person in control of CoNCERT Pharmaceuticals, Inc.

Transactions with Related Persons, Promoters and Certain Control Persons, page 50

22. We note your statement that Dr. Young is also the CEO and managing member of CorLyst, LLC. Please revise to clarify the percentage of time Dr. Young spends on your business, and if the time spent on other businesses is not immaterial, please expand your risk factor discussion to disclose this obligation.

Response

The Company has revised *Transactions with Related Persons, Promoters and Certain Control Persons* to clarify the percentage of time Dr. Young spends on the Company's business.

The Selling Stockholders, page 55

23. Revise your table to also include information relating to the percentage to be owned by security holders after completion of the offering to the extent such percentage is 1% or more. In addition, please disclose the relationship you have with PoC Capital, LLC, which appears to be the investor who is committed to fund up to $1.8 million of your clinical trial expenses. Refer to Item 507 of Regulation S-K.

Response

The Selling Stockholders table has been revised to show the percentage owned by the Selling Stockholders after completion of the offering. The Company has no relationship with PoC Capital, LLC other than PoC Capital, LLC being a third-party investor. The Company has noted the pledge of shares and warrants to the Company in the footnotes to the table.

Plan of Distribution, page 57

24. We refer to your statement that any pledgee of each selling stockholder may sell the shares covered by the registration statement, and we note that under your agreement with PoC Capital, PoC has pledged to you as collateral 50% of its securities received from its investment. If true, please revise to clarify the exclusion of these pledged securities from your statement. In addition, please tell us when the securities will be released from the pledge, and file your agreement with this investor as an exhibit to your registration statement, including all exhibits thereto.

Response

The Company has revised *Plan of Distribution* to exclude the Company as a pledgee, assignee or successor-in-interest who may sell shares covered by the registration statement. The Company's agreement with PoC Capital, LLC will be filed as an exhibit to the Company's upcoming Form 10-Q filing. In the discussion of the PoC Capital, LLC agreement, the Company has added disclosures regarding the pledged securities under *Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments* and in *Part II – Item 15. Recent Sales of Unregistered Securities*.

Financial Statements

Notes to Consolidated Financial Statements

Note 2 - Intangible Asset, page F-38

25. You disclose that the $11 million intangible asset recorded as of March 31, 2018 includes $3 million of costs capitalized to record an offset to a deferred tax liability related to the exercise of your option to acquire an exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for CTP-499. You also disclose on page F-41 that this deferred tax liability was created when CoNCERT sold its license and know-how to you for stock in a transaction under Section 351 of the Internal Revenue Code (Section 351 transaction) which treats the acquisition of the license and know-how as a tax-free exchange. Please provide us with a detailed analysis explaining how you determined that this transaction met the requirements to be considered a tax-free exchange under Section 351. In this regard, it would appear that under Section 351 an exchange would be considered tax free if (a) the property was exchanged solely for stock of the company and (b) immediately after the exchange the transferor controlled the company via 80% or more ownership of voting stock. Based on your beneficial ownership table on page 49, it appears that CoNCERT owns only 5.4% of your outstanding shares.

Response

In October 2017, Promet Therapeutics LLC., a Delaware limited liability company ("Promet"), and Processa Pharmaceuticals, Inc., formerly known as Heatwurx Inc. ("Processa") entered into an Asset Purchase Agreement (the "APA"), pursuant to which Processa acquired, in an Internal Revenue Code Section 351 tax-free contribution of assets solely for over 80% of the voting stock of Processa (the "Section 351 Transaction") by Promet, all of the properties, rights and assets, including liabilities and commitments, owned by Promet, directly or indirectly, in whole or in part, of every type and description, real, personal or mixed, tangible and intangible, wherever located and whether or not reflected on the books of Promet (the "Contributed Assets", and the transaction as a whole the "Promet/Processa Transaction").

Included in the Contributed Assets, Promet also transferred and contributed all, rights, title and interest under a certain option and license agreement with CoNCERT Pharmaceuticals, Inc. ("CoNCERT") with respect to certain know-how, patent rights and compounds developed or obtained by CoNCERT (the "CoNCERT Assets") for which voting securities of Processa were expressly contemplated to be issued as part and parcel with, and integrated into, the Section 351 transaction to CoNCERT because all Contributed Assets including 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 itself.

The APA was executed pursuant to authority granted by a "Unanimous Written Consent of the Board of Directors of Processa" dated in September 2017 which demonstrates that both Promet and Processa contemplated and intended that the Asset Purchase and the CoNCERT Assets were integral to one another and the recipients of equity, being Promet and CoNCERT, in connection therewith will control the Corporation for purposes of Section 351 and Section 368(c) in that they will own (i) at least 80% of the total combined voting power of all classes of stock entitled to vote and (ii) at least 80% of the total number of shares of all other classes of stock of the corporation. The Unanimous Written Consent demonstrates the transfer of all of Promet's assets, including but not limited to the transfer of any and all rights relating to the CoNCERT's Assets to Processa was meant to be an integrated transaction for tax purposes.

The Company structured, intended and expressly accepted that the transaction of Promet contributing its and the CoNCERT Assets solely for stock qualified for Section 351 treatment given that at the conclusion of the events both Promet and CoNCERT controlled more than 80% of the corporation immediately after the transactions were concluded. The 5.4% of the outstanding shares that were issued to CoNCERT were part of the overall 90% of the shares (more than the 80% "control" percentage pursuant to Code Section 368(c)) of Processa voting stock acquired as part of an integrated Section 351 Transaction whereby Processa acquired the Contributed Assets.

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.