



DIVISION OF  
CORPORATION FINANCE

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

August 28, 2018

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

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

Dear Dr. Young:

We have reviewed your 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.

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.

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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.

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.
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.

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.

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.

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.

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.

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.

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.

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.
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.
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.
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.
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.
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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

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Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

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 Sarmiento at 202-551-3798 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Neda Sharifi