



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.
Form 10-K for the Fiscal Year Ended December 31, 2017
Filed April 16, 2018 (as amended on April 17, 2018)
Form 10-Q for the Quarterly Period Ended March 31, 2018
Filed May 21, 2018
File No. 333-184948

Dear Dr. Young:

We have reviewed your filings 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 these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Annual Report on Form 10-K/A

Item 1. Business, page 3

1. Please expand your disclosure to explain how you identified NL and RIF in head and neck cancer patients as indications for which PCS-499 may result in clinical efficacy. Please also explain in terms a lay reader would understand what you mean that your product candidate is an "analog of an active metabolite," and disclose the drug that is already approved, the indication for which it was approved, and clarify whether it was approved by the FDA or another regulatory authority.
2. We note your statements 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 confirm that in future filings, you will revise your disclosures to remove all references about your product candidate's safety and efficacy, including statements regarding preliminary indications of efficacy (whether for your planned indication or other indications).

3. We refer to your statement that your business strategy is to identify drugs that can be "quickly" developed within "2-4 years." Please expand your disclosure to discuss the regulatory pathways you intend to pursue for your lead and other product candidates and their requirements. If you intend to rely on studies of third parties in seeking approval for PCS-499, identify the parties who performed the studies.

Intellectual Property, page 4

4. Please revise 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.

Asset Acquisitions by Licensing Agreements or Company Acquisitions, page 5

5. Please revise this section to discuss the material terms of your CoNCERT agreement and any other material license or collaboration agreements you may have at the time, 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 68 concerning CoNCERT's right to have one Board observer attend Promet's Board meetings. If CoNCERT has that right with respect to Processa's Board meetings, please discuss it here.

Item 1A. Risk Factors, page 9

6. Please add a risk factor to discuss the material risks associated with the fact that you do not have an audit or compensation committee, and that (according to the disclosure in your Registration Statement on Form S-1 filed on July 30, 2018) only one of your directors is independent.

We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. , page 19

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 26

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.

Item 10. Directors, Executive Officers and Key Employees, page 73

9. Please revise your disclosure 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.

Form 10-Q for the Quarterly Period Ended March 31, 2018

Notes to Consolidated Financial Statements

Note 2 - Intangible Asset, page 12

10. 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 15 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 of your Form S-1 filed on July 30, 2018, 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.

David Young
Processa Pharmaceuticals, Inc.
August 28, 2018
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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 A. Sharifi