November 8, 2022

Processa Pharmaceuticals

Processa Pharmaceuticals Announces Third Quarter Financial Results and Provides Corporate Update

- **PCS12852 successfully demonstrates a positive effect on the gastric emptying rate, clearing the path for a Phase 2B trial in 2023.**

- **Next Generation Capecitabine (a combination of PCS6422 and capecitabine) successfully identifies dosing regimens for a Phase 2B trial to be initiated in 2023 after a meeting with FDA to discuss the alignment of the trial design with the FDA's Project Optimus Oncology Initiative.**

HANOVER, Md., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a diversified clinical-stage company developing drugs for patients who have unmet medical conditions and/or require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the quarter ended September 30, 2022, and provided an update on its clinical programs.

Dr. David Young, President and CEO of Processa, commented, "We are delighted to report our push to enroll patients in PCS12852 (Gastroparesis) and PCS6422 (Next Generation Capecitabine) has helped us get critical data and report successful preliminary results in both trials. The data from these trials will help us design Phase 2B trials for both programs.

- Next Generation Capecitabine (NGC) (a combination of PCS6422 and capecitabine): we have identified lower capecitabine dosage regimens when administered in NGC that will help avoid dose-limiting toxicities such as hand-foot syndrome, yet provide approximately 50-times greater potency than capecitabine alone. We will complete this study in the near future and seek FDA confirmation of our plans to implement the principles of the Project Optimus Oncology Initiative, wherein the objective is to optimize dosing to achieve a better balance between efficacy and safety than merely using the maximum tolerated dose.

- PCS12852: we have shown a statistical difference in the gastric emptying rate between the 6 patients on 0.5 mg of PCS12852 and the 8 patients on placebo at p-value < 0.10 with mild to moderate adverse events. We anticipate having the analysis of the gastroparesis symptoms completed by the end of the year.

All our energies have been directed towards the completion of these trials that inform the next steps for these much-needed therapies.

Advancing these drugs in their respective clinical trial allows us to obtain the clinical data to better define each pivotal trial as well as provide us with more insight into how the FDA will

review each of these products as we plan the road maps for designing the studies for our New Drug Applications to FDA.

Financial Results for the Nine Months Ended September 30, 2022

Our cash balance on September 30, 2022, was $9.1 million, which should be sufficient to complete our three on-going clinical trials and fund our operations into the third quarter of 2023. During the nine months ended September 30, 2022, we spent $7.1 million in cash for these three clinical trials and in our operations. This is significantly less than our GAAP net loss of $14.4 million due to the effect of non-cash items like amortization and stock-based compensation, and the application of amounts we had prepaid to our CROs last year.

Our net loss for the nine months ended September 30, 2022, was $14.4 million or $0.90 per share compared to a net loss of $8.2 million, or $0.54 per share for the same period of 2021. The increase in our net loss relates primarily to increased clinical trial costs we incurred in our three ongoing trials. For the nine months ended September 30, 2022, we incurred $8.3 million in research and development costs, an increase of $3.5 million when compared to the same period of 2021. We anticipate clinical trial costs will continue to increase for the rest of the year as our trials continue to progress and we fund development activities for the other drugs in our pipeline.

During the nine months ending September 30, 2022, our general and administrative expenses totaled $6.1 million compared to $3.4 million for the same period in 2021. The increase related primarily to increases in non-cash or stock-based compensation costs, along with other operating and consulting costs. We allocated $6.1 million of non-cash compensation costs between our R&D and G&A costs, with the majority recorded as G&A.

Our net cash used in operating activities during the nine months ended September 30, 2022, increased by $1.1 million to $7.1 million, compared to $6 million for the same period in 2021. While we experienced increased GAAP costs related to our clinical trials and operations, we continued to make use of equity incentives to compensate our executive and development team, thereby reducing our cash outflow, and we were able to apply previously made advanced payments to our CROs against current trial costs.

As of September 30, 2022, we had 15.9 million common shares outstanding.

Conference Call Information

To participate in this event, please log-on or dial-in approximately 5 to 10 minutes before the beginning of the call.

Date: November 8, 2022
Time: 4:30 p.m. ET
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 178912
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/46906

Conference Call Replay Information
Toll-free: 877-481-4010

International: 919-882-2331
Replay Passcode: 46906
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/46906

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include Next Generation Capecitabine (formerly identified as PCS6422) for metastatic colorectal cancer and breast cancer, PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/gastroparesis). The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

For More Information:
Michael Floyd
mfloyd@processapharma.com
(301)651-4256

Patrick Lin
(925) 683-3218
plin@processapharma.com

Processa Pharmaceuticals

Source: Processa Pharmaceuticals, Inc.