

Processa Pharmaceuticals Announces Second Quarter 2022 Financial Results and Provides Corporate Update

- **PCS12852 on target to complete enrollment by September**
- **Expanded efforts to increase enrollment in PCS499 and PCS6422 showing results**

HANOVER, Md., Aug. 12, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a 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 June 30, 2022, and provided an update on its clinical programs.

Dr. David Young, President and CEO of Processa, commented, "Our efforts to enhance enrollment through adding new sites, extensive marketing campaigns and working with our CRO partners are showing results:

- We expect to close out enrollment for PCS12852 for Gastroparesis within the next month and present top-line data from the trial before the end of the year.
- We now have a sufficient number of patients in the screening queue for PCS6422 to complete our interim cohorts which we believe will provide valuable insights on de novo formation of DPD. We anticipate we will determine the maximum tolerated dose by early 2023.
- Patients are beginning to show a willingness to travel, and we are seeing increased patient activity in our PCS499 ulcerative necrobiosis lipoidica (uNL) trial. We are optimistic that we will enroll our interim analysis cohort before the end of the year.
- As part of our efforts to increase enrollment on our PCS499 trial, we recently launched a website to increase awareness of uNL and to inform patients of the ongoing Phase 2B Study of PCS499.

Advancing these 3 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 FDA will review each of these products when we submit the New Drug Applications to FDA."

Financial Results for the Six Months Ended June 30, 2022

Our cash balance on June 30, 2022, was \$12.1 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 six months ended June 30, 2022, we spent \$4.1 million in cash for these three clinical trials and our operations. This is significantly less than our GAAP net loss of \$8.4 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 six months ending on June 30, 2022, was \$8.4 million or \$0.53 per share compared to a net loss of \$5.3 million, or \$0.35 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 six months ended June 30, 2022, we incurred \$5.2 million in research and development costs, an increase of \$2.1 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 six months ending June 30, 2022, our general and administrative expenses totaled \$3.2 million compared to \$2.1 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 \$2.8 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 six months ended June 30, 2022, decreased by \$300,000 to \$4.1 million, compared to \$4.4 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 June 30, 2022, we had 15.8 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: August 11, 2022

Time: 4:30 p.m. ET

Toll Free: 877-545-0320

International: 973-528-0002

Entry Code: 623559

Live Webcast: <https://www.webcaster4.com/Webcast/Page/2572/46205>

Conference Call Replay Information

Toll-free: 877-481-4010

International: 919-882-2331

Replay Passcode: 46205

Replay Webcast: <https://www.webcaster4.com/Webcast/Page/2572/46205>

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 includes 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

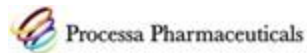
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Source: Processa Pharmaceuticals, Inc.