March 30, 2022

Processa Pharmaceuticals

Processa Pharmaceuticals Announces Year-End 2021 Results and Provides Corporate Update

Targeting Major Milestones 2022

HANOVER, Md., March 30, 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 that require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the year ended December 31, 2021, and provided a corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "Although COVID presented challenges for us and our industry in 2021, we commenced and enrolled patients in PCS499 for the treatment of uNL, PCS6422 (Next Generation Capecitabine) for the treatment of GI cancer, and received clearance for an IND for PCS12852 for gastroparesis. We were excited to learn that Next Generation Capecitabine is fifty times more potent than presently approved capecitabine and modified the protocol to further enhance the efficacy and safety of Next Generation Capecitabine. In addition, our modifications to the protocol now allow us to evaluate the possibility of treating patients using an individualized-personalized medicine approach for Next Generation Capecitabine. We completed the administrative efforts to commence our study in gastroparesis with the first patient to be dosed imminently. These efforts will produce three catalytic data events in the coming 9-10 months each in indications that could potentially exceed markets of $1 billion."

Recent Highlights and New Developments

- The Next Generation Capecitabine Phase 1B trial confirmed our hypothesis and provided insight into the importance of obtaining greater clarity on DPD inhibition and de novo formation, which could possibly lead to an individualized or personalized medicine approach to treating cancer patients.

- We have replaced non-performing sites and added remedial recruitment procedures to our PCS499 Phase 2B trial and expect to complete enrollment of the interim analysis cohort of patients mid-2022.

- We received clearance from FDA to proceed with a Phase 2A trial for the treatment of gastroparesis and anticipate enrolling the first patient in the first half of 2022 while completing the conduct of the trial in 2022.

- We are conducting a critical review of our clinical assets to assess opportunities to accelerate development and approval timelines.

Upcoming Clinical Drug Development Milestones

First half of 2022

- Phase 1B Restart recruitment with improved dosing regimen of PCS6422 (Cancer) and obtain a preliminary analysis of DPD inhibition and de novo formation timeline
- Phase 2B Interim analysis cohort enrolled for PCS499
- First Patient in (GI/gastroparesis) for PCS12852
- Complete initial development of biomarker assays for PCS3117

Second half of 2022

- Determine dosing regimens for Next Generation Capecitabine to potentially improve the efficacy and safety for treatment in patients with cancer (i.e., possible dosing regimens for both PCS6422 and capecitabine)
- Interim Cohort analysis and complete enrollment for PCS499
- Complete enrollment and provide top-line data Q4'22 - Q1'23 for PCS12852
- Define regulatory approval development paths for PCS3117 and PCS11T

Financial Results for the Year Ended December 31, 2021

We continue to manage our cash efficiently and as of December 31, 2021 we had a cash balance of $16.5 million. During the year ending on December 31, 2021 we increased our cash balance by $1.1 million compared to December 31, 2020 by raising net proceeds of $9.8 million in a private placement in early 2021 and in our ATM offering offset by $8.7 million in costs we incurred related to our three clinical trials and our spending for operating and other related costs.

We define overhead as our general and administrative expenses plus the salaries for our development and administrative teams. Our cash outlay for overhead expenses for the year ended December 31, 2021 was only $3.0 million. We accomplished this in part by having the cash portion of our six executive team members totaling only $525,000 for 2021. We are focused on directing our cash toward activities that move our drug products forward.

For the year ending on December 31, 2021 we reported a net loss of $11.4 million, or $0.75 per share compared to a net loss of $14.4 million, or $2.54 per share for the same period of 2020. The primary reduction in our net loss was due a decline in licensing activity in 2021 versus 2020. During 2021 we licensed PCS3117 from Ocuphire Pharma. Inc. for cash and stock totaling $567 thousand while in 2020, we incurred. $8.7 million related to licensing PCS12852 from Yuhan Pharmaceuticals, PCS6422 from Elion Oncology and PCS11T from Aposense. Adjusting for in-process research and development acquisition costs, our net loss increased by $5.1 million for the year ended December 31, 2021 compared to the comparable period in 2020. This increase primarily relates to increased clinical trial costs we incurred as we progress with our clinical trials.

During the year ended December 31, 2021, we incurred research and development expenses totaling $6.9 million compared to $3.2 million for the same period in 2020. The increase in our R&D costs of $3.7 million in 2021 was primarily due to costs we incurred related to our active clinical trials. Our general and administrative expenses totaled $4.7 million for the year ended December 31, 2021 compared to $3.3 million for the same period in 2020. The increase related primarily to increases in professional and other consulting fees, as well as non-cash stock-based compensation. Allocated between our R&D and G&A costs is $3.4 million of non-cash compensation costs.

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: March 30, 2022
Time: 4:30 p.m. ET
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 837465
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/44826

Conference Call Replay Information

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 44826
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/44826

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: PCS6422 (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 registration statement relating to the securities being sold in this offering, which identifies important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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