November 12, 2020

Processa Pharmaceuticals Announces Third Quarter 2020 Results, Provides Corporate Update

Highlights include closing $19.2 million public offering, uplisting to Nasdaq, and positive progress with multiple candidates currently in Processa's clinical drug pipeline

HANOVER, MD., Nov. 12, 2020 (GLOBE NEWSWIRE) -- via InvestorWire -- Processa Pharmaceuticals, Inc. (NASDAQ: PCSA) ("Processa" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life for patients who have unmet medical needs or conditions or who have no alternative treatment, today reports financial results for the third quarter of 2020.

Dr. David Young, CEO and chairman of Processa, commented, "The third quarter was a period of tremendous value creation. Over that time, we in-licensed important clinical drug candidates PCS12852 and PCS6422, uplisted to Nasdaq and closed a $19.2 million public offering. Due to those achievements, we now have sufficient funds to complete three trials for three distinct markets, each exceeding $1 billion. Importantly, we are developing products for which existing clinical evidence of efficacy has already been established. With key milestones to announce over the next 12-18 months, including interim data for PCS6422 in 3Q21 and PCS499 in 4Q21, we are excited about the near-term opportunity of increasing shareholder value."

Recent Highlights and New Developments

- Entered into an exclusive licensing agreement with Elion Oncology, Inc. to develop, manufacture and commercialize eniluracil (PCS6422) globally. PCS6422 is an oral drug to be administered with fluoropyrimidine cancer drugs (e.g., capecitabine, 5-FU). PCS6422 is designed to decrease the breakdown of the cancer drugs, which, without such intervention, reduce to inactive metabolites or metabolites that are known to cause unwanted side effects and to interfere with the anticancer activity.
- Entered into a licensing agreement with Yuhan Corporation, a publicly traded South Korean company, to license PCS12852, a small molecule drug in development for the treatment of functional gastrointestinal (GI) disorders (FGID).
- Appointed Dr. Khalid Islam to the Company's board of directors.
- Appointed Michael Floyd as the Company's chief operating officer.
- Uplisted to Nasdaq.
- Closed an underwritten public offering of 4,800,000 shares of common stock for a price to the public of $4.00 per share. Net proceeds to the Company were approximately $17.1 million.

Upcoming Clinical Drug Development Milestones

1H 2021

- Phase 1B First Patient Dosed: PCS6422 (Cancer)
- Phase 2B First Patient Dosed: PCS499 (Ulcerative NL)
- FDA IND Submission: PCS12852 (GI/Gastroparesis)

2H 2021

- Interim Cohort Results Begin: PCS6422
- Interim Results: PCS499
- Phase 2A First Patient Dosed: PCS12852

Financial Results for the Third Quarter Ended Sept. 30, 2020

General and administrative expenses were approximately $423 thousand for the quarter ended Sept. 30, 2020, compared to approximately $419 thousand during the third quarter ended Sept. 30, 2019.

Research and development expense totaled approximately $533 thousand for the third quarter ended Sept. 30, 2020, compared to approximately $585 thousand during the third quarter ended Sept. 30, 2019.

Net loss attributable to common stockholders for the third quarter ended Sept. 30, 2020 was $3.1 million, compared to $864 thousand for the third quarter ended Sept. 30, 2019.

As of Sept. 30, 2020, the Company had cash and cash equivalents of approximately $325 thousand. Subsequent to the quarter end, Processa closed a $19.2 million gross proceeds public offering of common stock resulting in net proceeds of approximately $17.1 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Following the close of the offering and related transactions the Company will have 13.8 million common shares outstanding.

Conference Call Information

To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call.

Date: Nov. 12, 2020
Time: 5:30 p.m. ET
Dial-In Information: Toll Free: 877-876-9176
International: 785-424-1670

Live Webcast: **https://www.webcaster4.com/Webcast/Page/2572/38528**

Conference Call Replay Information

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 38528

Replay Webcast: **https://www.webcaster4.com/Webcast/Page/2572/38528**

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 used these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active 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 that 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 that could cause actual results to differ from those contained in the forward-looking statements.

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