Processa Pharmaceuticals

Processa Pharmaceuticals Announces Year end 2020 Results and Provides Corporate Update

Clinical drug pipeline is funded and targeting major milestones in 2021

HANOVER, March 25, 2021 (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 announces financial results for the year ended December 31, 2020, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "2020 was a transformational year for our company; we in-licensed three exciting programs with potential markets exceeding $1 billion for each drug, improved our balance sheet, strengthened our management team and Board, up-listed to Nasdaq, and prepared the foundation for successful execution for our three clinical stage programs. I am delighted to report that we anticipate the first patients to be dosed with PCS6422 and PCS499 in the second quarter of 2021 with interim data for PCS6422 near the end of Q3 and for PCS499 in the first quarter of 2022."

Recent Highlights and New Developments

- Selected 5 U.S. clinical sites to enroll patients with ulcerative necrobiosis lipoidica for our Phase 2B trial "A Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of PCS499 in Treating Ulcerations in Patients who Have Necrobiosis Lipoidica." Two to three additional clinical sites will be selected in the future including sites outside the U.S.

- Entered into an exclusive licensing agreement with Elion Oncology, Inc. to develop, manufacture and commercialize PCS6422 (eniluracil) 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 gastroparesis and functional gastrointestinal motility disorders.

- Entered into a licensing agreement with Aposense LTD to license PCS11T, a pro-drug of SN38, the active metabolite of the widely used cancer drug irinotecan, that deposits SN38 in the membranes of cancer cells preferentially over normal cells.

- 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 with net proceeds of $17.1 million.

- In February 2021 we closed a private placement with institutional and accredited investors for $10.2 million. We sold 1,321,132 shares of the common stock at a purchase price of $7.75 per share for $10.2 million in the private placement and received net proceeds of $9.9 million.

Upcoming Clinical Drug Development Milestones

First half of 2021

- Phase 1B First Patient Dosed: PCS6422 (Cancer)

- Phase 2 First Patient Dosed: PCS499 (Ulcerative NL)

Second half of 2021

- FDA IND Submission: PCS12852 (GI/Gastroparesis)

- Interim Cohort Results Begin: PCS6422

First half of 2022

• Interim Results: PCS499

• Phase 2A First Patient Dosed: PCS12852

Financial Results for the Year Ended December 31, 2020

General and administrative expenses were $3.3 million compared to $1.6 million for the year ended December 31, 2019. The increase in our general and administrative expenses was primarily due to stock-based compensation.

Research and development expenses totaled $3.2 million compared to $2.3 million for the year ended December 31, 2019.

We also recorded $8.7 million dollars of costs as the acquisition of in-process research and development related to licensing agreements we executed for PCS6422, PCS12852 and PCS11T. A total of $8.6 million of this amount was non-cash consideration.

Our net loss was $14.4 million, compared to a net loss of $3.4 million for the year ended December 31, 2019. During 2020 we recorded non-cash expenses of $8.6 million for acquired in-process research and development and $2.7 million of stock-based compensation costs.

As of December 31, 2020, the Company had cash and cash equivalents of $15.4. In February 2021, we closed a $10.2 million private placement receiving net proceeds of $9.9 million.

Following the close of the offering and related transactions the Company will have 15.5 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: March 25, 2021
Time: 5:30 p.m. ET
Toll Free: 877-545-0320; Entry Code: 805295
International: 973-528-0016; Entry Code: 805295

Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/40452

Conference Call Replay Information

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 40452

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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