CytRx Comments on Quarterly Results and Recent Strategic Initiatives

LOS ANGELES--(BUSINESS WIRE)--CytRx Corporation (OTCQB:CYTR) (“CytRx” or the “Company”), a specialized biopharmaceutical company focused on research and development for the oncology and neurodegenerative disease categories, today commented on its results for the second quarter ended June 30, 2021. In addition, CytRx recapped corporate developments as well as matters pertaining to its agreements with ImmunityBio, Inc. (NASDAQ:IBRX) (“ImmunityBio”) and Orphazyme A/S (NASDAQ:ORPH) ("Orphazyme"). The Company’s 10-Q was filed today.

Steven A. Kriegsman, Chairman and Chief Executive Officer of CytRx, commented:

"We took important steps to enhance our capital position and further strengthen our corporate governance during the second quarter. By raising gross proceeds of $10 million from our recent financing, we have obtained valuable working capital that can help us maintain stability as we efficiently manage our portfolio of licensing agreements and high-potential assets. We continue to believe in the long-term promise of our licensed drugs and Centurion Biopharma. We look forward to monitoring Orphazyme’s pursuit of European regulatory approval for arimoclomol in Q4 2021 and ImmunityBio’s Q1 2022 release of Cohort C survival data from its QUILT 88 study, which is a Phase 2 pancreatic cancer trial that includes aldoxorubicin."

First Quarter Financial Overview

- CytRx concluded the quarter ended June 30, 2021 with cash on hand of approximately $8.4 million.
- The Company recorded a net loss of $1.2 million for the quarter ended June 30, 2021, compared to a net loss of $1.3 million for the same period in 2020.
    - General and administrative expenses were $1.2 million for the quarter, compared with $1.4 million for the same period in 2020.

Recent Developments

Corporate Highlights

- Last month, CytRx entered into a securities purchase agreement with a healthcare-focused institutional investor, resulting in aggregate gross proceeds of approximately $10 million. The investor is independent of the Company’s Board of Directors and management team. The Company intends to use the net proceeds for working capital purposes.
- Last month, Jennifer K. Simpson, Ph.D joined the Company’s Board of Directors. Dr. Simpson is the Chief Executive Officer and a Director of Panbela Therapeutics Inc. (NASDAQ: PBLA), a clinical stage drug development company. Shortly after joining Panbela Therapeutics, Dr. Simpson led a public financing with an uplist to the NASDAQ exchange. She has more than 13 years’ experience in pharmaceutical executive leadership, global marketing and product commercialization.
- With respect to Centurion Biopharma, Mr. Kriegsman and Lead Director Louis Ignarro, PhD continued pursuing strategic partnership opportunities to advance clinical testing for the platform’s assets. Discussions with prospective partners under confidentiality agreements are ongoing. There are no formal updates to report at this time.
- CytRx maintains federal and state net operating loss (“NOL”) carryforwards of $327.6 million and $252.6 million, respectively, available to offset against future taxable income. Of this amount, $258.3 million of federal NOLs and $252.6 million of state NOLs are unrestricted.

ImmunityBio Highlights

- ImmunityBio announced during the quarter that Cohort C of its QUILT 88 study in pancreatic cancer, which includes aldoxorubicin and patients who have previously failed two lines of standard-of-care therapy, is expected to be completed in the third quarter of 2021. An early readout of survival data is expected in the first quarter of 2022.

Orphazyme Highlights

- Orphazyme announced during the quarter that it received a Complete Response Letter ("CRL") from the Food and Drug Administration ("FDA") following its review of the new drug application for arimoclomol. Orphazyme disclosed that the FDA issued the CRL based on needing additional evidence to further substantiate the validity and interpretation of the 5-domain NPC Clinical Severity Scale and, in particular, the swallow domain. Further, the FDA noted in the CRL that additional data is needed to bolster confirmatory evidence beyond the single phase 2/3 clinical trial to support the benefit-risk assessment of the NDA.

- Subsequently, Orphazyme announced 24-month interim results of an open-label extension (“OLE”) trial of arimoclomol for the treatment of NPC. Orphazyme provided efficacy and safety data for its investigational treatment arimoclomol in NPC for up to 36 months. The results demonstrate that arimoclomol provided a sustained benefit to study participants by reducing NPC progression as measured by the 5-domain NPC Clinical Severity Scale (5D-NPCCSS).

- Orphazyme is expecting prospective European regulatory approval for arimoclomol in the treatment of NPC by the end of 2021.

About CytRx

CytRx Corporation (OTCQB: CYTR) is a biopharmaceutical company with expertise in discovering and developing new therapeutics principally to treat patients with cancer and neurodegenerative diseases. CytRx’s most recent advanced drug conjugate, aldoxorubicin, is an improved version of the widely used anti-cancer drug doxorubicin and has been out-licensed to ImmunityBio, Inc. (NASDAQ: IBRX). In addition, CytRx's drug candidate, arimoclomol, was sold to Orphazyme A/S (Nasdaq: ORPH) in exchange for milestone payments and royalties. Orphazyme is developing arimoclomol in Niemann-Pick disease Type C ("NPC") and Gaucher disease. Learn more at www.cytrx.com.

Forward-Looking Statements

This press release contains forward-looking statements. These statements are not historical facts, but instead represent only CytRx’s belief regarding future events, many of which, by their nature, are inherently uncertain and outside of CytRx’s control. Forward-looking statements include statements relating to the potential receipt of EMA and FDA approval of arimoclomol and the CytRx’s potential receipt of future milestone and royalty payments from Orphazyme. Such statements involve risks and uncertainties that could cause actual events or results to differ materially from the events or results described in the forward-looking statements, including risks and uncertainties relating to the ability of Orphazyme to obtain regulatory approval for, manufacture and commercialize its products and therapies that use arimoclomol; the results of clinical trials involving arimoclomol; the amount, if any, of future milestone and royalty payments that we may receive from Orphazyme; and other risks and uncertainties described in the most recent annual and quarterly reports filed by the CytRx with the SEC, including disclosures under the heading “Risk Factors”, and current reports filed since the date of the CytRx’s most recent annual report. All forward-looking statements are based upon information available to the CytRx on the date the statements are first published. The CytRx undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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