LadRx Corporation Issues Corporate Update for 3Q22

November 17, 2022 09:00 AM Eastern Standard Time

LOS ANGELES--(BUSINESS WIRE)--LadRx Corporation (OTCQB: LADX) ("LadRx" or the "Company"), a biopharmaceutical innovator focused on research and development of life-saving cancer therapeutics, today issued the below update to stockholders.

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Dear Stockholders,

Welcome to LadRx's latest update for the quarter ending September 30, 2022. Please see our 10Q filed on November 10, 2022, for detailed financial reporting and analysis.

As a reminder, the Company has developed a chemotherapeutic delivery system called LADR (Linker-Activated Drug Release). LADR is a small organic molecule that can be attached to chemotherapeutic agents in order to target the delivery and release of the chemotherapeutic agent to solid cancers. The LADR-mediated targeting of chemotherapeutics to cancers could be reasonably expected to increase the amount of chemotherapeutic that can be safely dosed in a human (or in some cases allow for safe use of chemotherapeutics too powerful to be used without targeted delivery), and to reduce off-target side effects attributable to the chemotherapeutic agent.

The first-gen LADR-based chemotherapeutic that is most advanced is Aldoxorubicin. Aldoxorubicin is composed of the first-gen LADR molecule linked to the widely-used chemotherapeutic agent doxorubicin. Aldoxorubicin has proven the concept of LADR in that it can be dosed several times higher than doxorubicin, with fewer side effects. The Company out-licensed Aldoxorubicin to Immunity Bio, and Aldoxorubicin is currently in human clinical trials (see below).

The next-gen LADR-based drugs employ an improved linker. The Company's current pre-clinical drug candidates are based on this next-gen LADR design, namely LADR7-10. LADR7 and 8 employ the highly potent chemotoxin Auristatin E, while LADR9 and 10 employ another highly potent chemotoxin called Maytansine.

LADR7

During Q3, we continued to move LADR7 towards IND in the most capital-efficient way possible. The IND-enabling activities for LADR7 at this stage include a full inventory of IND-enabling data generated thus far for LADR7, and developing the strategy for completing the IND-enabling work for LADR7, as well as dovetailing that strategy into future LADR products. As we have stated previously, we are pleased with the amount and quality of IND-enabling work that has been completed for LADRs7-10, and we feel that the IND-enabling work remaining for LADR7 is minimal. The next steps for LADR7 are to manufacture clinical-grade product, and to perform basic toxicology studies using the clinical-grade material (toxicology studies have already been performed with non-clinical-grade material). It is our current opinion that successful completion of these activities will position LADR7 for submission of an IND to the FDA. The steps of clinical-grade manufacture and final toxicology are expected to cost approximately $2M in direct costs, so we will not initiate this work until further funding is received (variations to this estimate can be expected as the project initiates).

Aldoxorubicin

The Company has out-licensed the development and commercialization of Aldoxorubicin to Immunity Bio (NASDAQ:IBRX) for approximately $343M in milestones and additional royalties on sales (dependent on certain regulatory approvals, which are not guaranteed). Immunity Bio recently announced that they have completed enrollment in a registrational-intent Phase II in pancreatic cancer, and have scheduled a Type B meeting with the FDA in December of 2022. In the same release (see Immunity Bio Overview Presentation, November 2022), Immunity Bio indicated that a Phase II in glioblastoma is planned. We look forward to continued updates from Immunity Bio's testing of Aldoxorubicin in these two very high-need patient populations.

Arimoclomol

The Company's non-oncology asset, Arimoclomol, was out-licensed to Orphazyme for the treatment of Nieman-Pick Type C, a neurological disease. In May of 2022, after receiving a Complete Response Letter from the FDA, Orphazyme's assets were purchased by KemPharm Denmark A/S, a wholly-owned subsidiary of KemPharm, Inc. In KemPharm's most recent update on Arimoclomol, KemPharm stated, "…Based on the recent completion of the 4-year open-label safety trial, the ongoing and constructive dialogue with the FDA and the new wealth of data generated since the CRL, we now anticipate resubmitting the updated NDA as early as Q3 2023. And, while no new or unanticipated issues related to resubmission have arisen, we believe the added time will be well-spent in preparation of an NDA filing with the highest likelihood of approval." The Company's agreement with KemPharm could, if milestones are achieved, bring up to $120M to LadRx and additional royalties on sales.

Financial Results

The Company worked diligently during the quarter to maximize our runway for the current cash, while we seek additional capital through multiple pathways. The Company is operating very efficiently, and management now estimates that current cash is sufficient to fund operations to approximately mid-2Q2023. This runway estimate includes no revenues from licensed products, and very little expenditure (or progress) on LADR product development. Despite very challenging capital market conditions, the Company continues its efforts to bring in additional capital through the least expensive means possible, and plans to continue to operate the Company efficiently.

Thank you for your continued support of LadRx, and we look forward to continuing to update you on our progress.

Stephen Snowdy, Ph.D.
Chief Executive Officer
LadRx Corporation

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Forward-Looking Statements

This press release may contain certain statements relating to future results which are forward-looking statements. These statements are not historical facts, but instead represent only LadRx's belief regarding future events, many of which, by their nature, are inherently uncertain and outside of LadRx's control. 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; and other risks and uncertainties described in the most recent annual and quarterly reports filed by LadRx with the SEC, including disclosures under the heading "Risk Factors", and current reports filed since the date of LadRx's most recent annual report. All forward-looking statements are based upon information available to LadRx on the date the statements are first published. LadRx undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

About LadRx

LadRx Corporation (OTCQB: LADX) is a biopharmaceutical company with expertise in discovering and developing new therapeutics principally to treat patients with cancer. LadRx'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. In addition, LadRx's drug candidate, Arimoclomol, was sold to Orphazyme A/S in exchange for milestone payments and royalties. KemPharm is currently focused on developing Arimoclomol in Niemann-Pick disease Type C (NPC). LadRx Corporation's website is www.ladrxcorp.com.

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