



AcelRx Pharmaceuticals Announces Divestment of DSUVIA® to Alora Pharmaceuticals

Mar 14, 2023

Agreement with Alora Pharmaceuticals provides AcelRx with 15% royalties on commercial sales, 75% royalties on Department of Defense (DoD) sales, up to \$116.5 million in potential sales-based milestone payments, and a strong commercial partner experienced with commercialization in hospital settings

Divestment allows AcelRx to prioritize resources on its late stage development assets, led by Niyad™, the lead nafamostat program with breakthrough device designation status from FDA

Near-term corporate milestones expected by the end of Q2 2023 include the Niyad Emergency Use Authorization submission and the filing of a new drug application for the first of our two pre-filled syringe product candidates

HAYWARD, Calif., March 14, 2023 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced the divestment of its FDA-approved drug, DSUVIA® to Alora Pharmaceuticals (Alora). The agreement allows AcelRx to participate in the long-term value expected to be created by Alora as they expand the commercialization of DSUVIA.

The agreement provides AcelRx with a 15% royalty on commercial sales of DSUVIA, a 75% royalty on sales of DSUVIA to the Department of Defense, DSUVIA's single largest customer, and up to \$116.5 million in sales-based milestones. Closing of the transaction is expected by the end of the month, and AcelRx will provide, and be reimbursed for, transition services during a period of up to 6 months post-closing. In exchange for the 75% royalty on net sales to the DoD, AcelRx will lead the relationship to ensure continued engagement and expected expansion of sales to the DoD. Importantly, the divestment will allow for AcelRx to focus its operations and capital on its late stage, high-value asset programs, with specific prioritization of its lead nafamostat program, Niyad™, as an anticoagulant for the extracorporeal circuit with peak sales potential of \$200M.

AcelRx expects Alora will continue to build on AcelRx's previous focus on procedural suites, with the employment of AcelRx's existing sales representatives at closing, and the utilization of a number of their own existing sales representatives that will also expand into the hospital and surgery center settings, which both companies believe to be the largest market opportunity for DSUVIA.

"As stated previously, our goal has been to find a partner for DSUVIA who is better resourced and has the experience to expand the sales of DSUVIA to the hospital and surgery center markets and to build on our current momentum in the procedural suites. In addition, we believe the opportunity to maintain our relationship with the DoD will benefit all parties and leverage years of effort and education into incremental value for our shareholders," stated Vince Angotti, Chief Executive Officer of AcelRx. "We believe that Alora is in a great position to deliver value given their expertise in commercializing products in hospitals, experience with manufacturing and selling controlled substances, and a seasoned commercial team across their group of companies of over 200 people."

Mr. Angotti continued, "The divestment of DSUVIA marks a new chapter in the evolution of AcelRx enabling our laser focus on the advancement of our high-value, late-stage development assets led by Niyad. In particular, we have progressed our lead nafamostat product candidate, Niyad™ to prepare for an Emergency Use Authorization (EUA) submission in this first half of 2023. In addition, we expect to submit our first ephedrine pre-filled syringe NDA in the first half of this year. This transaction also allows us to continue to reduce operating expenses while sharing in the continued value of DSUVIA. We believe that the divestment of DSUVIA, plus the advancement of both our nafamostat and pre-filled syringe portfolio programs, builds long-term value for our shareholders and sets us on the path to a new era for the Company with multiple late-stage, and potentially commercial stage assets within the next 12 months."

"We are proud to partner with AcelRx to continue the growth and distribution of DSUVIA to ensure access by patients. This product will help Alora Pharmaceuticals expand our pain management portfolio. DSUVIA provides an effective solution for patients in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, with management of acute pain severe enough to require an opioid analgesic," said Art Deas, CEO of Alora Pharmaceuticals, LLC.

About Alora Pharmaceuticals, LLC

Alora Pharmaceuticals, LLC is the parent company of six specialty pharmaceutical and pharmaceutical manufacturing companies. Alora is headquartered in Alpharetta, GA. Alora is the parent company of the following organizations that comprise the Alora family of companies, Avion Pharmaceuticals, Acella Pharmaceuticals, Osmotica Pharmaceuticals, Sovereign Pharmaceuticals, Trigen Laboratories and Vertical Pharmaceuticals.

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, branded as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. DSUVIA/DZUVEO was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA/DZUVEO is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile, when delivered sublingually, avoids the high peak plasma levels and short duration of action observed with IV administration. DZUVEO has been approved by the European Medicines Agency and AcelRx's European commercialization partner, Aguetant, markets the drug in Europe.

For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

About Nafamostat

Nafamostat is a broad spectrum, synthetic serine protease inhibitor with anticoagulant, anti-inflammatory and potential anti-viral activities. Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that will be investigated and developed as a potential anti-viral for the treatment of COVID, acute respiratory distress syndrome (ARDS), disseminated intravascular coagulation (DIC) and acute pancreatitis.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and several product candidates. The product candidates include: Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S. being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings; two pre-filled, ready-to-use syringes of ephedrine and phenylephrine licensed for the U.S. from Aguetant; Niyad™, a regional anticoagulant for the extracorporeal circuit; and LTX-608, for the potential treatment of COVID-19, disseminated intravascular coagulation, acute respiratory distress syndrome and acute pancreatitis. DZUVEO is an approved product in Europe.

This release is intended for investors only. For additional information about AcelRx, please visit www.acelrx.com.

Forward-looking statements

This press release contains forward-looking statements based upon AcelRx's current expectations. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "potential," "believe," "expect," "expects," "expected," "create," "created," "anticipate," "may," "will," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "estimates," "benefits," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including: (i) risks relating to AcelRx's product development activities and ongoing commercial business operations; (ii) risks related to AcelRx's commercial partner's success; (iii) risks related to the ability of AcelRx and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iv) risks related to unexpected variations in market growth and demand for AcelRx's and its business partner's commercial and developmental products and technologies; (v) risks related to AcelRx's liquidity and our ability to maintain capital resources; (vi) AcelRx's ability to retaining its listing on the Nasdaq exchange; and (vii) risks relating to our ability to obtain regulatory approvals for our developmental product candidates. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere in AcelRx's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC) and any subsequent public filings. You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.



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