AcelRx Announces Rebranding With Name Change to Talphera, Inc.

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Name change to "Talphera" reflects a new era of the Company in partnership with the medical community developing novel solutions for medically supervised settings

Talphera will begin trading on Nasdaq under the trading symbol "TLPH" effective January 10

SAN MATEO, Calif., Jan. 9, 2024 /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 rebranding of the Company, with a name change to Talphera, Inc. ("Talphera"). The rebrand decision was made to reflect the Company's strategy of developing and commercializing products to support advancing care to optimize outcomes in medically supervised settings, moving beyond the original focus on acute pain. The Company's lead nafamostat product candidate, Niyad, is expected to have a Premarket Approval (PMA) submission to the FDA in the second half of 2024.

The name Talphera was derived from "Talisman", meaning a strong leader, and reflects the new "pharmaceutical era" for the Company. The company's new mission at Talphera is to support healthcare providers by developing and commercializing products in medically supervised settings that deliver advances in care to patients. Talphera will commence trading on the Nasdaq Global Market under the ticker symbol "TLPH" effective January 10, 2024.

"We were a company founded on acute pain treatments with the understanding that patient outcomes depend on the quality of the tools available to a patient's medical team. This understanding remains the focal point of our product candidates in development. Rebranding to Talphera represents a new era of the company where we have a broader mission to develop and commercialize innovative therapies for use in medically supervised settings beyond acute pain," said Vince Angotti, Chief Executive Officer of Talphera.

Talphera's lead product candidate, Niyad, has been granted FDA Breakthrough Designation and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit. If approved, Niyad would be the first-ever regional anticoagulant approved by the FDA for use in the dialysis circuit.

Talphera expects to initiate the registrational study of Niyad™, the NEPHRO CRRT (**N**afamostat **E**fficacy in **Ph**ase 3 **R**egistrati**o**nal **C**ontinuous **R**enal **R**eplacement **T**herapy) Study, shortly. The study has already received central Institutional Review Board (IRB) approval. The study is designed as a prospective, double-blinded trial to be conducted at up to 10 U.S. hospital intensive care units. The study will enroll and evaluate 166 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk for bleeding. The primary endpoint of the study is mean post-filter activated clotting time using Niyad versus placebo over the first 24 hours. Key secondary endpoints include filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours.

The first patient is expected to be enrolled for the NEPHRO study in the first quarter of 2024. Since the end of last year, the company has completed all sponsor actions and is awaiting activation from registered sites. A PMA submission for Niyad is expected to be filed with the FDA in the second half of 2024.

About Talphera, Inc.

Talphera, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. Talphera's lead product candidate, 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. Talphera is also developing two pre-filled syringes in-licensed from its partner Aguettant: Fedsyra™, a pre-filled ephedrine syringe, and PFS-02, a pre-filled phenylephrine syringe. This release is intended for investors only. For additional information about Talphera, please visit www.talphera.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.

Forward-Looking Statements

This press release contains forward-looking statements based upon Talphera'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," "expects," "expected," "anticipate," "awaiting," "may," "will," "would," "seek," "approximately," "if," "intends," "intended," "plans," "planning," "estimates," or the negative of these words or other comparable terminology. The discussion of 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 Talphera's product development activities and ongoing commercial business operations; (ii) risks related to the ability of Talphera and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iii) risks related to unexpected variations in market growth and demand for Talphera's commercial and developmental products and technologies; (iv) risks related to Talphera's liquidity and its ability to maintain

capital resources sufficient to conduct the required clinical studies; (v) Talphera's ability to retain its listing on the Nasdaq exchange; and (vi) risks relating to Talphera's ability to obtain regulatory approvals for its 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 Talphera'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 Talphera's most recent annual, quarterly or current report as filed or furnished with the SEC. Talphera's SEC reports are available at www.Talphera.com under the "Investors" tab. Except to the extent required by law, Talphera 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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