



## Talphera Announces Achievement of 17 Patient Enrollment Milestone in NEPHRO CRRT Pivotal Trial

Aug 25, 2025

*The NEPHRO CRRT pivotal trial has now reached approximately 25% enrollment, driven by the recent acceleration in the recruitment rate from new profile clinical sites*

*On track for planned study completion by the end of 2025*

SAN MATEO, Calif., Aug. 25, 2025 /PRNewswire/ -- Talphera, Inc. (Nasdaq: TLPH), ("Talphera"), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced the enrollment of 17 patients in its 70-patient pivotal NEPHRO CRRT clinical trial. The enrollment of 17 patients is a milestone that was required to be achieved, and announced, as one of the conditions to close the second tranche of the three-tranche financing announced in March 2025.

"Approximately one week after announcing we had enrolled 15 patients, we've now reached the 17-patient enrollment milestone. The continued acceleration in the study enrollment rate, combined with the six new sites expected to begin enrolling during the third quarter reinforces our confidence in reaching our forecasted study completion by the end of the year," stated Vince Angotti, CEO of Talphera. "The re-launch of the study with new target profile clinical sites and principal investigators is yielding positive results, as evidenced by over 90% of enrolled patients now coming from the new target profile sites. We're excited that we're able to demonstrate that the time and effort invested in re-launching the study was the right path forward, and our previously communicated timeline to complete the study remains intact."

### About the NEPHRO CRRT Study

The NEPHRO CRRT Study, which has received central IRB approval, is designed as a prospective, double-blinded trial to be conducted at up to 14 U.S. hospital intensive care units. The study will enroll and evaluate 70 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 the mean post-filter activated clotting time over 72 hours, 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.

### About Niyad and 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 IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. Talphera's registrational study of Niyad™ is named the NEPHRO CRRT Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy) study. An ICD-10 procedural code, XY0YX37, has been issued for the extracorporeal introduction of nafamostat. The ICD-10 code is a specific/billable code that can be used to indicate a procedure. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that may be investigated and developed for the treatment of acute respiratory distress syndrome (ARDS), disseminated intravascular coagulation (DIC), acute pancreatitis or as an anti-viral treatment, amongst other potential targets.

### 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 (IDE) as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA).

This release is intended for investors only. For additional information about Talphera, please visit [www.talphera.com](http://www.talphera.com)

### Forward-looking statements

This press release contains forward-looking statements based upon Talphera's current expectations and assumptions. 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 "believe," "expect," "anticipate," "may," "if," "intends," "plans," "potential," "projected," "will," or the negative of these words or other comparable terminology, and include: Talphera's expectation that the NEPHRO CRRT study will complete enrollment by the end of the year, and six new sites expected to begin enrolling during the third quarter. Talphera's discussion of its strategy, plans and intentions 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, including that clinical studies may not be fully enrolled or completed and/or confirm any safety, efficacy or other potential developmental product characteristics described or assumed in this press release; (ii) Talphera's developmental product candidates may not be beneficial to patients or healthcare providers or be successfully commercialized; (iii) risks relating to Talphera's ability to obtain regulatory approvals for its developmental product candidates; (iv) risks related to the ability of Talphera and its business partners to implement development plans, commercial launch plans, forecasts and other business expectations; and (v) risks related to Talphera's liquidity and its ability to maintain capital resources sufficient to conduct its clinical studies. 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 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](http://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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