



Talpheria Announces Agreement with the FDA to Reduce the NEPHRO CRRT Study Size to 70 Patients From 166 and a Private Placement Financing Priced At-the Market of up to \$14.8 Million

Mar 31, 2025

The U.S. Food and Drug Administration (FDA) agreed to reduce the number of patients in the NEPHRO CRRT study from 166 to 70 patients, of which 6 patients are already enrolled

Talpheria believes the NEPHRO CRRT study should be completed by the end of 2025

Existing investors, Nantahala Capital and Rosalind Advisors led the capital commitment priced at-the-market as defined by Nasdaq rules

\$4.925 million in gross proceeds at first closing with the potential to receive an additional \$9.85 million across two \$4.925 million tranches upon achieving certain patient enrollment milestones

Cash and investments at December 31, 2024 of \$8.9 million, together with the expected proceeds from the financing of up to \$14.8 million should provide capital through targeted completion of the NEPHRO CRRT study by the end of 2025

SAN MATEO, Calif., March 31, 2025 /PRNewswire/ -- Talpheria, Inc. (Nasdaq: TLPH), (Talpheria), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced its agreement with the FDA to reduce the size of the NEPHRO CRRT study to 70 patients from the 166 previously included in the study protocol. The Company also announced it has entered into securities purchase agreements with certain institutional investors and a member of management for the sale and issuance of shares of common stock and pre-funded warrants in lieu of shares to purchase common stock in a three-tranche private placement for potential gross proceeds of up to \$14.8 million.

"We are pleased that the FDA agreed with our assessment to reduce the study size to 70 patients, which still keeps the study's primary endpoint powered at 90%," stated Vince Angotti, Talpheria CEO. "This change, along with the other protocol changes to the study inclusion criteria and the addition of new sites with higher enrollment potential will support a timely completion of the study, which we are targeting by the end of the year. We are also thankful for the continued support from our existing investors, Nantahala and Rosalind, which led the private placement financing. The additional capital should support our objective of completing the study by the end of the year as we look forward to submitting our PMA early next year and a potential approval in the second half of 2026."

The Private Placement

The private placement is led by Nantahala Capital and Rosalind Advisors, and includes a member of management, and has the potential to raise gross proceeds of up to \$14.8 million, which amount includes (i) \$4.925 million in the first closing (which is expected to occur on April 2, 2025), (ii) \$4.925 million in a second closing upon the enrollment of at least 17 patients in the Company's NEPHRO CRRT study (the "Second Milestone"), and a minimum stock price of at least \$0.7325 per share for five consecutive days following a public announcement of the achievement of the Second Milestone, and (iii) \$4.925 million in a third closing upon the enrollment of at least 35 patients (the "Third Milestone"), and a minimum stock price of at least \$0.7325 per share for five consecutive days following a public announcement of the achievement of the Third Milestone.

In the first closing, Talpheria will issue 3,405,118 shares of common stock and 4,999,316 pre-funded warrants, at a price of \$0.586 per share and \$0.585 per pre-funded warrant, respectively. The pre-funded warrants will have an exercise price of \$0.001 per share. In each of the second and third closings upon achievement of the respective milestones and if closing conditions are met, Talpheria expects to issue an additional 3,405,118 shares of common stock and 4,999,316 pre-funded warrants, at a price of \$0.586 per share and \$0.585 per pre-funded warrant, respectively.

The offer and sale of the securities described above are being offered and sold in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and Regulation D promulgated thereunder, and have not been registered under the Act, or applicable state securities laws. Accordingly, such securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

The Company has agreed to file a registration statement under the Act with the Securities and Exchange Commission (the "SEC"), covering the resale of the shares of common stock to be issued in the private placement and the shares of common stock underlying the pre-funded warrants no later than 45 days following the closing date, and to use reasonable best efforts to have the registration statement declared effective as promptly as practical thereafter, and in any event no later than 90 days following the closing date in the event of a "full review" by the SEC.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

About Talpheria, Inc.

Talpheria, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. Talpheria'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 Talpheria, please visit www.talpheria.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 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 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.

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," "potentially," "believe," "expect," "anticipate," "may," "will," "if," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "targeted," "estimates," "sufficient," "benefits," or the negative of these words or other comparable terminology, and include Talphera's statements regarding and include Talphera's statements regarding a potential completion of the NEPHRO CRRT study by the end of 2025; Talphera's expectation that the committed capital from the financing, upon completion of certain milestones and meeting certain closing conditions, should provide sufficient capital to fund the completion of the study expected by the end of 2025, with an expected PMA application submitted in early 2026 and a potential approval in the second half of 2026; and Talphera's ability to successfully meet the enrollment goals and minimum stock price to achieve the Second Milestone and Third Milestone. 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 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.talpheracom 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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SOURCE Talphera, Inc.

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