Talphera Announces Private Placement Financing of up to $29 Million Priced At-the Market

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CorMedix is making a strategic investment in Talphera as the lead investor, supported by existing stockholders Nantahala, Rosalind and Rock Springs with several new institutional investors

$17 million in proceeds at first closing with the potential to receive an additional $12 million across one additional tranche upon the achievement of the primary endpoint in the NEPHRO clinical study

The completion of this financing is expected to provide the company with sufficient capital through the planned approval of a Niyad PMA in the second half of 2026

SAN MATEO, Calif., Sept. 8, 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 it has entered into securities purchase agreements with CorMedix Inc. and certain institutional investors for the sale and issuance of shares of common stock and pre-funded warrants in lieu of shares to purchase common stock in a private placement for total potential proceeds of up to $29 million. CorMedix is making a strategic investment in Talphera common stock priced at the market, while the institutional investors will purchase common stock and pre-funded warrants in lieu thereof, priced at the market, in an initial closing and with an additional tranche of $12 million upon achievement of the primary endpoint in the NEPHRO CRRT study, and the company's stock trading at a minimum agreed price.

"We are pleased we have secured funding that provides us with the opportunity to be fully funded through a potential approval of the Niyad PMA, which is anticipated in the second-half of next year," stated Vince Angotti, Talphera CEO. "The strong interest in this financing, particularly from CorMedix, who recognizes the potential value of Niyad in the acute care market, as well as our existing and new institutional investors, further enforces our strong belief that nafamostat is a valuable product for physicians as they currently have no ideal options for anticoagulation for CRRT. If approved, Niyad would become the first available FDA-approved regional anticoagulant for CRRT. Furthermore, the accelerated momentum in enrollment in our NEPHRO CRRT clinical study provides continued confidence in our goal to complete the study by the end of the year," continued Angotti.

The Private Placement

The private placement is led by CorMedix Inc (Nasdaq: CRMD), a commercial stage pharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions, and includes institutional investors Nantahala Capital, Rosalind Advisors, and Rock Springs Capital, and has the potential to raise gross proceeds of up to $29 million, which amount includes (i) $17 million in the first closing (which is expected to occur on September 10, 2025), (ii) $12 million in a second closing with such institutional investors upon the achievement of the primary endpoint in the Company's NEPHRO CCRT study (the "Milestone Event"), and a minimum stock price of at least $0.6875 per share for five consecutive days following a public announcement of the achievement of the Milestone Event.

In the first closing, Talphera will issue 25,036,363 shares of common stock and 5,845,455 pre-funded warrants, at a price of $0.55 per share and $0.549 per pre-funded warrant, respectively. The pre-funded warrants will have an exercise price of $0.001 per share. In the second closing, upon achievement of the Milestone Event and if closing conditions are met, Talphera expects to issue additional shares of common stock and pre-funded warrants in the amount of $12 million, at a price of $0.55 per share and $0.549 per pre-funded warrant, respectively, with the allocation between common stock and prefunded warrants to be determined at that time.

In connection with the closing of this transaction, the Company has provided CorMedix with a 60-day period of exclusivity following the announcement of the achievement of the primary endpoint and topline clinical study results from the NEPHRO CRRT clinical study to negotiate a definitive agreement to acquire Talphera. CorMedix also has the right to nominate a representative to the Talphera Board of Directors.

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 15 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 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.

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 (**N**afamostat **E**fficacy in **Ph**ase 3 **R**egistrational **C**ontinuous **R**enal **R**eplacement **T**herapy) 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 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 company through a planned approval of the Niyad PMA expected in the second half of 2026; and Talphera's ability to successfully meet the primary endpoint in its clinical study to achieve the Milestone Event. 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.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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