Talphera Announces First Quarter 2026 Financial Results and Provides Corporate Update

May 13, 2026

NEPHRO CRRT clinical study expected to be completed this year

Cash and investments of $21.1 million at March 31, 2026

Conference call and webcast to be held on Wednesday, May 13, 2026 at 4:30 pm ET

SAN MATEO, Calif., May 13, 2026 /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 first quarter 2026 financial results and provided a corporate update.

"In early March, we announced the attainment of 50% enrollment in the NEPHRO CRRT study evaluating nafamostat. With continued steady enrollment, we have well exceeded this level, and continue to expect study completion later this year," stated Vince Angotti, CEO of Talphera. "Our clinical study sites and principal investigators remain focused on enrollment and delivering a high quality study as they are eager for a potential alternative anticoagulant for Continuous Renal Replacement Therapy (CRRT). The investor and analyst event held in March also highlighted the need for an alternative, given the disadvantages of the currently used products, heparin and citrate. If approved, we continue to believe nafamostat will fill an unmet need in the market as a regional anticoagulant for CRRT," continued Angotti.

First Quarter 2026 and Recent Highlights

- In March 2026, announced reaching the 35-patient enrollment milestone, representing 50% enrollment in the NEPHRO CRRT study. Enrollment has continued to increase since this announcement, with study completion expected in 2026.
- In March 2026, held an investor and analyst event with two key opinion leaders (KOLs) focused on anticoagulants used during CRRT and the potential for nafamostat to address an unmet need.
- In March 2026, two posters were presented at the 31st Annual International Conference on Advances in Critical Care Nephrology (AKI & CRRT 2026), entitled: "*A Randomized, Placebo-Controlled Multi-Center Study of the Safety and Efficacy of Niyad in Patients Undergoing Continuous Renal Replacement Therapy Who Cannot Tolerate Heparin or Are at a Higher Risk of Bleeding*" and, "*In Vivo Assessment of Nafamostat, A Novel Regional Anticoagulant in a Porcine Model AKI and CKRT*".
- In March 2026, closed $4.1 million third tranche of the March 2025 private placement financing upon achieving the 35-patient enrollment milestone and other conditions.

First Quarter 2026 Financial Information

- The cash and investments balance was $21.1 million as of March 31, 2026.
- Combined R&D and SG&A expenses for the first quarter of 2026 totaled $3.9 million compared to $2.9 million for the first quarter of 2025. Excluding non-cash stock-based compensation expense, these amounts were $3.7 million for the first quarter of 2026, compared to $2.7 million for the first quarter of 2025. The increase in combined R&D and SG&A expenses in the first quarter of 2026 was primarily due to higher Niyad® development expenses, reflecting increased enrollment, and an increase in certain G&A expenses.
- Net loss attributable to common shareholders for the first quarter of 2026 was $2.6 million, or $0.04 per basic and diluted share, compared to a net loss of $2.6 million, or $0.10 per basic and diluted share, for the first quarter of 2025.

Conference Call and Webcast

Talphera will hold a conference call and webcast at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time today to discuss the results and provide an update on the Company's business.

Investors who wish to participate in the conference call may do so by dialing 1-800-836-8184 for North American callers, or 1-646-357-8785 (toll applies) for international callers outside of Canada. The conference ID is 24180. The webcast can be accessed here or by visiting the Investors section of the Company's website at www.talphera.com and clicking on the webcast link posted within Investors/News & Events/Upcoming Events section. The webcast will include a slide presentation and a replay will be available on the Talphera website for 90 days following the event.

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 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 (**N**afamostat **E**fficacy in

Phase 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 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 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 the NEPHRO CRRT clinical study will be completed later this year, and Talphera's belief that nafamostat will fill an unmet need in the market as a regional anticoagulant for CRRT. 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 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.

Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31	
	2026	**2025**
Statement of Operations Data		
Revenue	$ -	$ 27
Operating costs and expenses:		
Research and development [1]	1,650	1,169
Selling, general and administrative [1]	2,298	1,774
Total operating costs and expenses	3,948	2,943
Loss from operations	(3,948)	(2,916)
Other expense, net:		
Interest income and other income, net	169	69
Gain on change in fair value of warrant liability	1,223	181
Total other expense, net	1,392	250
Net loss from continuing operations	(2,556)	(2,666)
Net income from discontinued operations	-	73
Net loss	$ (2,556)	$ (2,593)
Net loss per share attributable to stockholders:		
Basic and diluted, continuing operations	$ (0.04)	$ (0.10)
Basic and diluted, discontinued operations	$ -	$ 0.00
Basic and diluted loss per share	$ (0.04)	$ (0.10)
Shares used in computing net loss per share of common stock, basic and diluted	69,822	26,268

(1) Includes the following non-cash stock-based compensation expense:

Research and development	$ 64	$ 77
Selling, general and administrative	150	119
Total	$ 214	$ 196

Selected Balance Sheet Data
(in thousands)

	March 31, 2026 (Unaudited)	December 31, 2025[1] (Unaudited)
Cash, cash equivalents and investments	$ 21,108	$ 20,381
Total assets	30,155	29,719
Total liabilities	11,677	12,684
Total stockholders' equity	18,478	17,035

[1] Derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less stock-based compensation expense)

	Three Months Ended March 31 (in thousands) (unaudited)	
	2026	**2025**
Operating expenses (GAAP):		
Research and development	$ 1,650	$ 1,169
Selling, general and administrative	2,298	1,774
Total operating expenses	3,948	2,943
Less stock-based compensation expense	214	196
Operating expenses (non-GAAP)	$ 3,734	$ 2,747

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