Talphera Announces Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Update

Mar 23, 2026

Previously announced achievement of 50% enrollment of the NEPHRO CRRT clinical study in March 2026 and closed the associated financing tranche of $4.1 million

All 12 clinical study sites now able to enroll patients to support an expected study completion in 2026

Cash and investments of $20.4 million at December 31, 2025

Virtual investor and analyst day with business updates to be held on Monday, March 23, 2026 at 11:00 am ET

SAN MATEO, Calif., March 23, 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 fourth quarter and full year 2025 financial results and provided a corporate update.

"Earlier this month, we communicated reaching the 35-patient enrollment mark in the 70-patient nafamostat registrational study for CRRT. Since then, we have added two more target profile clinical sites, and are continuing to enroll patients at a pace to enable completion of the study later this year," stated Vince Angotti, CEO of Talphera. "Our target profile clinical sites and principal investigators remain highly motivated, driving over 90% of enrollment to date, and they are excited by the prospect of having nafamostat potentially approved for use during CRRT, given their dissatisfaction with the current anticoagulants currently being used for CRRT. Later today, we are hosting a live virtual investor and analyst webcast where you will hear directly from two principal investigators in the NEPHRO CRRT registrational study and their experiences with CRRT, the currently available anticoagulants for CRRT, and how they see nafamostat potentially filling an unmet need."

Fourth Quarter 2025 and Recent Highlights

- Reached the 35-patient enrollment milestone or 50% enrollment in the NEPHRO CRRT study.
- All 12 clinical sites are now able to enroll patients and are expected to support increased enrollment rates for the remainder of the NEPHRO CRRT clinical study.
- Closed $4.1 million third tranche of the March 2025 private placement financing upon achieving the 35-patient enrollment milestone and other conditions.
- In October 2025, certain purchasers waived the conditions of the securities purchase agreement dated March 31, 2025, to effect both the second and third closings of the private placement with respect to such purchasers only, resulting in aggregate gross proceeds to Talphera of approximately $1.6 million.

Fourth Quarter 2025 Financial Information

- The cash and investments balance was $20.4 million as of December 31, 2025.
- Combined R&D and SG&A expenses for the fourth quarter of 2025 totaled $3.5 million compared to $3.0 million for the fourth quarter of 2024. Excluding non-cash stock-based compensation expense, these amounts were $3.3 million for the fourth quarter of 2025, compared to $2.8 million for the fourth quarter of 2024. The increase in combined R&D and SG&A expenses in the fourth quarter of 2025 was primarily due to increases in costs associated with Niyad development and certain G&A expenses.
- Net loss attributable to common shareholders for the fourth quarter of 2025 was $3.8 million, or $0.06 per basic and diluted share, compared to a net loss of $1.9 million, or $0.07 per basic and diluted share, for the fourth quarter of 2024.

2026 Guidance

- Cash operating expenses, or selling, general and administrative, and research and development expenses, excluding stock-based compensation, are expected to be in the range of $17 million to $18 million in 2026, which includes the expenses related to finalizing the NEPHRO CRRT registration trial later this year. This is an increase from approximately $13 million in 2025, which is driven by the NEPHRO CRRT study and related CMC expenses and validation batches expected to be incurred prior to the filing of a Premarket Approval (PMA) with the FDA.

Virtual Investor and Analyst Day Information

Talphera will hold a Virtual Investor and Analyst Day webcast at 11:00 a.m. Eastern Time/8:00 a.m. Pacific Time today to provide a business update and hear two principal investigators in the NEPHRO CRRT study provide their experiences with CRRT, the current anticoagulants being used during CRRT today and how they see nafamostat filling an unmet need in that market.

Investors and analysts who wish to participate in the webcast should register 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.

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 **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 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 two new high profile sites will support increased enrollment rates for an expected study completion later in 2026, that Talphera's expected cash operating expenses will be in the $17 million to $18 million range for 2026. 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 December 31		Year Ended December 31	
	2025	**2024**	**2025**	**2024**
Statement of Operations Data				
Revenue	$ -	$ -	$ 28	$ -
Operating costs and expenses:				
Research and development [1]	1,561	1,323	6,033	6,718
Selling, general and administrative [1]	1,892	1,673	7,479	8,534
Total operating costs and expenses	3,453	2,996	13,512	15,252
Loss from operations	(3,453)	(2,996)	(13,484)	(15,252)
Other expense, net:				
Interest income and other income, net	203	103	436	679
Gain on sale of future payments	-	-	-	1,246
(Loss) gain on change in fair value of warrant liability	(522)	1,023	(1,315)	717
Non-cash interest expense on liability related to sale of future payments	-	-	-	(394)
Total other expense, net	(319)	1,126	(879)	2,248
Net loss from continuing operations	(3,772)	(1,870)	(14,363)	(13,004)

Net income from discontinued operations	-	-	73	-
Net loss	$ (3,772)	$ (1,870)	$ (14,290)	$ (13,004)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.06)	$ (0.07)	$ (0.34)	$ (0.50)
Basic and diluted, discontinued operations	$ -	$ -	$ 0.00	$ -
Basic and diluted loss per share	$ (0.06)	$ (0.07)	$ (0.34)	$ (0.50)
Shares used in computing net loss per share of common stock, basic and diluted	66,954	26,238	42,411	25,846

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

Research and development	$ 57	$ 91	$ 246	$ 375
Selling, general and administrative	128	139	453	614
Total	$ 185	$ 230	$ 699	$ 989

Selected Balance Sheet Data
(in thousands)

	December 31, 2025	December 31, 2024[1]
	(Unaudited)	(Unaudited)
Cash, cash equivalents and investments	$ 20,381	$ 8,863
Total assets	29,719	18,236
Total liabilities	12,684	10,235
Total stockholders' equity	17,035	8,001

[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, 2024.

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

	Three Months Ended December 31 (unaudited)		Year Ended December 31 (unaudited)	
	2025	**2024**	**2025**	**2024**
Operating expenses (GAAP):				
Research and development	$ 1,561	$ 1,323	$ 6,033	$ 6,718
Selling, general and administrative	1,892	1,673	7,479	8,534
Total operating expenses	3,453	2,996	13,512	15,252
Less stock-based compensation expense	185	230	699	989
Operating expenses (non-GAAP)	$ 3,268	$ 2,766	$ 12,813	$ 14,263

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SOURCE Talphera, Inc.

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