Talphera Reports Third Quarter 2026 Financial Results and Provides Business Update

Nov 12, 2026

Briefing document submitted to FDA for a Sprint Meeting requesting a close of the NEPHRO CRRT study enrollment based on number of patients enrolled as of December 31, 2026

Pivotal NEPHRO study currently exceeds 80% power for primary endpoint supporting a potential early close of enrollment

Updated market research raises nafamostat peak sales estimate for CRRT above $200 million

Cash and investments of $14.2 million at September 30, 2026

Conference call and webcast to be held on Thursday, November 12, 2026 at 4:30 p.m. ET

SAN MATEO, Calif., Nov. 12, 2026 /PRNewswire/ -- Talphera, Inc. (Nasdaq: TLPH) ("Talphera"), a specialty pharmaceutical company developing nafamostat as a regional anticoagulant for use in continuous renal replacement therapy (CRRT), today announced financial results for the third quarter of 2026 and provided a business update. The update covers Talphera's proposed PMA filing plan for nafamostat and its increased commercial opportunity.

"We believe nafamostat has the potential to address an important unmet need as a regional anticoagulant for critically ill patients undergoing CRRT," stated Vince Angotti, CEO of Talphera. "Our updated market research, including physician feedback on nafamostat compared with currently used products, supports its potential adoption in CRRT and an increased peak sales estimate of more than $200 million."

Vince Angotti continued, "Enrollment in the NEPHRO CRRT study has slowed over recent months, primarily due to fewer qualifying patients at our clinical sites. Enrolling these critically ill patients is challenging and other recent CRRT studies having faced similar difficulties. Some sponsors closed enrollment early and subsequently received regulatory approval."

"To date, we have enrolled more than 75% of the planned 70 patients. To support our goal of completing the study this year, we have submitted a briefing document to the FDA seeking feedback on closing enrollment as of December 31, 2026, even if fewer than the targeted 70 patients are enrolled. While the study remains blinded and open for enrollment, we believe the current enrollment is sufficient to support a PMA filing as it has over 80% statistical power for the primary endpoint," concluded Vince Angotti.

Third Quarter 2026 and Recent Highlights

- Submitted a briefing document to the FDA seeking feedback on a regulatory strategy for a PMA filing based on final NEPHRO CRRT study enrollment as of December 31, 2026, even if fewer than the targeted 70 patients are enrolled.
- Increased estimated peak sales for nafamostat in CRRT to more than $200 million, based on updated qualitative and quantitative market research.

Third Quarter 2026 Financial Information

- The cash and investments balance was $14.2 million as of September 30, 2026.
- Combined R&D and SG&A expenses for the third quarter of 2026 totaled $4.1 million compared to $3.4 million for the third quarter of 2025. Excluding non-cash stock-based compensation expense, these amounts were $3.8 million for the third quarter of 2026, compared to $3.3 million for the third quarter of 2025. The increase in combined R&D and SG&A expenses in the third quarter of 2026 was primarily due to increased Niyad development project activities, and certain SG&A expenses related to pre-launch commercial preparation activities.
- Net loss attributable to common shareholders for the third quarter of 2026 was $4.0 million, or $0.05 per basic and diluted share, compared to a net loss of $4.4 million, or $0.11 per basic and diluted share, for the third quarter of 2025.
- Talphera plans to file a Form S-3 Shelf Registration Statement to replace its existing Form S-3 that expires on November 30, 2026.

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.

Conference Call and Webcast Information

- Date: Thursday, November 12, 2026 at 4:30 PM ET/1:30 PM PT
- Participant Dial-in (North America): 1-800-836-8184
- Participant Dial-in (International): 1-646-357-8785
- Conference ID: 69368
- Webcast Access: Click here

The event can also be accessed in the Upcoming Events page in the Investors section of the Talphera website at www.talphera.com.

A replay of the webcast will be available on the Talphera website for 90 days after 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 **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 is designed as a prospective, double-blinded trial to be conducted at up to 14 U.S. hospital intensive care units. The study is intended to 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. The study is powered over 90% for the primary endpoint with 70 patients. 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", "estimate", "anticipate", "may", "if", "intends", "plans", "potential", "projected", "will", or the negative of these words or other comparable terminology, and include: Talphera's belief that the current enrollment in the NEPHRO CRRT clinical study which provides more than 80% statistical power for the primary endpoint supports its proposed strategy for an early close of enrollment as of December 31, 2026, subject to FDA's feedback; Talphera's estimate of peak sales of nafamostat exceeding $200 million; Talphera's updated market research on CRRT treatment patterns and its favorable impact on the market opportunity for nafamostat; 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 September 30		Nine Months Ended September 30	
	2026	**2025**	**2026**	**2025**
Statement of Operations Data				
Revenue	$ -	$ 1	$ -	$ 28
Operating costs and expenses:				
Research and development [1]	2,189	1,803	5,529	4,472
Selling, general and administrative [1]	1,947	1,620	6,479	5,587
Total operating costs and expenses	4,136	3,423	12,008	10,059
Loss from operations	(4,136)	(3,422)	(12,008)	(10,031)
Other income (expense), net:				
Interest income and other income, net	138	81	479	233
(Loss) gain on change in fair value of warrant liability	(20)	(1,095)	643	(793)
Total other income (expense), net	118	(1,014)	1,122	(560)

Net loss from continuing operations	(4,018)	(4,436)	(10,886)	(10,591)
Net income from discontinued operations	-	-	-	73
Net loss	$ (4,018)	$ (4,436)	$ (10,886)	$ (10,518)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.05)	$ (0.11)	$ (0.15)	$ (0.31)
Basic and diluted, discontinued operations	$ -	$ -	$ -	$ -
Basic and diluted loss per share	$ (0.05)	$ (0.11)	$ (0.15)	$ (0.31)
Shares used in computing net loss per share of common stock, basic and diluted	75,544	41,453	73,652	34,140

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

Research and development	$ 72	$ 57	$ 207	$ 189
Selling, general and administrative	220	95	542	325
Total	$ 292	$ 152	$ 749	$ 514

Selected Balance Sheet Data
(in thousands)

	September 30, 2026 (Unaudited)	December 31, 2025[1] (Unaudited)
Cash, cash equivalents and investments	$ 14,157	$ 20,381
Total assets	23,574	29,719
Total liabilities	12,862	12,684
Total stockholders' equity	10,712	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 September 30 (in thousands) (unaudited)		Nine Months Ended September 30 (in thousands) (unaudited)	
	2026	**2025**	**2026**	**2025**
Operating expenses (GAAP):				
Research and development	$ 2,189	$ 1,803	$ 5,529	$ 4,472
Selling, general and administrative	1,947	1,620	6,479	5,587
Total operating expenses	4,136	3,423	12,008	10,059
Less stock-based compensation expense	292	152	749	514
Operating expenses (non-GAAP)	$ 3,844	$ 3,271	$ 11,259	$ 9,545

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