Talphera Announces Second Quarter 2026 Financial Results and Provides Corporate Update

Aug 12, 2026

NEPHRO CRRT clinical study of nafamostat is 75% enrolled; expected to be complete this year

Draft 2026 KDIGO guidelines added nafamostat as an acceptable CRRT anticoagulant, a positive change from previous guidelines

Updated market research indicates an estimated 200,000 annual U.S. CRRT procedures, a 21% increase over prior estimates; investor event planned as enrollment nears completion

Cash and investments of $17.1 million at June 30, 2026

Conference call and webcast to be held on Wednesday August 12, 2026 at 4:30 pm ET

SAN MATEO, Calif., Aug. 12, 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 financial results for the second quarter of 2026 and provided a corporate update on the development of nafamostat.

"Reaching 75% enrollment in the NEPHRO CRRT study keeps us on track for completion by year-end," stated Vince Angotti, CEO of Talphera. "Site realignment is complete, with all target clinical sites now activated. We are particularly pleased with the high level of engagement from our principal investigators and study site personnel."

"In addition, the evolving treatment landscape continues to reinforce the potential role for nafamostat in CRRT. The KDIGO 2026 Clinical Practice Guideline for Acute Kidney Injury (AKI) and Acute Kidney Disease (AKD) is currently pending final publication following the close of its public comment period in May. The guideline references nafamostat as an acceptable regional anticoagulant during CRRT. This is a positive change from KDIGO's last published AKI guidelines," continued Mr. Angotti. "Separately, our updated market research on CRRT treatment patterns indicates that approximately 200,000 CRRT procedures will be performed in 2027 in the U.S., an increase of 21% over our prior estimate. As we near completion of enrollment, we look forward to hosting an investor event to share these findings and discuss the commercial opportunity for nafamostat, if approved, including the potential favorable implications of the evolving KDIGO guidelines."

Second Quarter 2026 and Recent Highlights

- 75% enrollment in the NEPHRO CRRT clinical study which is expected to be completed this year.
- Completed our clinical site realignment, with all target clinical sites now activated.
- KDIGO published its 2026 guideline and completed a public comment period, citing nafamostat as an acceptable CRRT anticoagulation alternative, a positive change from the last published recommendations. KDIGO (Kidney Disease: Improving Global Outcomes) is the global non-profit organization developing and implementing evidence-based clinical practice guidelines in kidney disease.
- Completed updated market research indicating approximately 200,000 annual U.S. CRRT procedures in 2027, a 21% increase over prior estimates.
- Regained Nasdaq compliance with the $1 bid price rule.

Second Quarter 2026 Financial Information

- The cash and investments balance was $17.1 million as of June 30, 2026.
- Combined R&D and SG&A expenses for the second quarter of 2026 totaled $3.9 million compared to $3.7 million for the second quarter of 2025. Excluding non-cash stock-based compensation expense, these amounts were $3.7 million for the second quarter of 2026, compared to $3.5 million for the second quarter of 2025. The increase in combined R&D and SG&A expenses in the second quarter of 2026 was primarily due to higher Niyad development expenses, reflecting increased enrollment.
- Net loss attributable to common shareholders for the second quarter of 2026 was $4.3 million, or $0.06 per basic and diluted share, compared to a net loss of $3.5 million, or $0.10 per basic and diluted share, for the second 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.

Conference Call and Webcast Information

- Date: Wednesday, August 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: 50873
- 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 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, Talphera's belief that the KDIGO 2026 Clinical Practice Guideline for Acute Kidney Injury (AKI) and Acute Kidney Disease (AKD) has potential favorable implications for the commercial opportunity for nafamostat, 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 June 30		Six Months Ended June 30	
	2026	**2025**	**2026**	**2025**
Statement of Operations Data				
Revenue	$ -	$ -	$ -	$ 27
Operating costs and expenses:				
Research and development [1]	1,690	1,500	3,340	2,669
Selling, general and administrative [1]	2,234	2,193	4,532	3,967
Total operating costs and expenses	3,924	3,693	7,872	6,636
Loss from operations	(3,924)	(3,693)	(7,872)	(6,609)
Other (expense) income, net:				
Interest income and other income, net	172	83	341	152
(Loss) gain on change in fair value of warrant liability	(560)	121	663	302
Total other (expense) income, net	(388)	204	1,004	454

Net loss from continuing operations	(4,312)	(3,489)	(6,868)	(6,155)
Net income from discontinued operations	-	-	-	73
Net loss	$ (4,312)	$ (3,489)	$ (6,868)	$ (6,082)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.06)	$ (0.10)	$ (0.09)	$ (0.20)
Basic and diluted, discontinued operations	$ -	$ -	$ -	$ -
Basic and diluted loss per share	$ (0.06)	$ (0.10)	$ (0.09)	$ (0.20)
Shares used in computing net loss per share of common stock, basic and diluted	75,527	34,530	72,690	30,422

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

Research and development	$ 71	$ 55	$ 135	$ 132
Selling, general and administrative	172	111	322	230
Total	$ 243	$ 166	$ 457	$ 362

Selected Balance Sheet Data
(in thousands)

	June 30, 2026 (Unaudited)	December 31, 2025[1] (Unaudited)
Cash, cash equivalents and investments	$ 17,076	$ 20,381
Total assets	26,806	29,719
Total liabilities	12,400	12,684
Total stockholders' equity	14,406	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 June 30 (in thousands) (unaudited)		Six Months Ended June 30 (in thousands) (unaudited)	
	2026	**2025**	**2026**	**2025**
Operating expenses (GAAP):				
Research and development	$ 1,690	$ 1,500	$ 3,340	$ 2,669
Selling, general and administrative	2,234	2,193	4,532	3,967
Total operating expenses	3,924	3,693	7,872	6,636
Less stock-based compensation expense	243	166	457	362
Operating expenses (non-GAAP)	$ 3,681	$ 3,527	$ 7,415	$ 6,274

View original content to download multimedia:https://www.prnewswire.com/news-releases/talphera-announces-second-quarter-2026-financial-results-and-provides-corporate-update-302850056.html

SOURCE Talphera, Inc.

Investor Contacts: Talphera, Raffi Asadorian, CFO, 650-216-3500, investors@talphera.com; LifeSci Advisors, Kevin Gardner, 617-283-2856, kgardner@lifesciadvisors.com