Talphera Announces Second Quarter 2025 Financial Results and Provides Corporate Update

Aug 14, 2025

New sites accelerate registrational study enrollment - 15 patients have been enrolled in the NEPHRO study which remains on track with completion projected by the end of the year

Cash and cash equivalents at June 30, 2025 were $6.8 million

Conference call and webcast to be held Thursday, August 14, 2025 at 4:30 pm ET

SAN MATEO, Calif., Aug. 14, 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 second quarter 2025 financial results and provided a corporate update.

"We have enrolled 15 patients in the NEPHRO clinical study and based on the recent accelerated rate of enrollment, we expect to complete the study by the end of the year," stated Vince Angotti, CEO of Talphera. "In the last six weeks, we have gained enrollment momentum from the new target profile clinical sites and study protocol changes. New sites have enrolled 90% of patients to date, providing confidence that we are on the right path. To further accelerate the positive enrollment trend, we expect to add six new clinical sites by the end of the third quarter, bringing the total number of sites up to 13, including nine with our target profile. We're excited about the recent progress of the study, and importantly, the consistent feedback from our sites that they are eager for nafamostat to be available as their preferred alternative to current CRRT anticoagulation products."

Second Quarter 2025 and Recent Highlights

- As announced today, the Company has enrolled 15 patients in the NEPHRO clinical study, supporting the expected completion timeline of the clinical study by the end of 2025, and a planned PMA submission in the first quarter of 2026, assuming enrollment and site activation trends continue. 13 total clinical sites are anticipated by the end of the third quarter, which include four legacy sites, three currently enrolling target profile sites, and six new target profile sites that are expected to be enrolling patients in the third quarter.
- In April 2025, Talphera announced the closing of the first tranche of $4.9 million of a three-tranche financing for up to $14.8 million, including two committed tranches which will close upon achievement of 17 and 35 enrolled patients, and if Talphera's stock price trades at a price at or above $0.7325 for five consecutive days following the announcement of achieving the enrollment milestones. These conditions may be waived by the investors at any time. The financing was led by existing investors, Nantahala Capital and Rosalind Advisors, and includes a member of management.

Second Quarter 2025 Financial Information

- The cash and cash equivalents balance was $6.8 million as of June 30, 2025.
- Combined R&D and SG&A expenses for the second quarter of 2025 totaled $3.7 million compared to $4.3 million for the second quarter of 2024. Excluding non-cash stock-based compensation expense, these amounts were $3.5 million for the second quarter of 2025, compared to $4.0 million for the second quarter of 2024. The decrease in combined R&D and SG&A expenses in the second quarter of 2025 was primarily due to reductions in personnel expense and other general and administrative expenses.
- For the second quarter of 2025, the Company recognized net loss from continuing operations of $3.5 million, as compared to net loss of $3.8 million for the second quarter of 2024, largely due to reductions in personnel expense in 2025 and the change in fair value of the Company's warrant liability, partially offset by the gain on sale of future payments in 2024. The divestment of DSUVIA represents a discontinued operation; accordingly, all historical operating results for the business are reflected within discontinued operations. There were no DSUVIA related expenses in the second quarter of 2025 or 2024.
- Net loss attributable to common shareholders for the second quarter of 2025 was $3.5 million, or $0.10 per basic and diluted share, compared to a net loss of $3.8 million, or $0.15 per basic and diluted share, for the second quarter of 2024.

2025 Expense Guidance

- Cash operating expenses, or selling, general and administrative, and research and development expenses, excluding stock-based compensation, is expected to be in the range of $16 million to $17 million in 2025, which includes the expenses related to executing and completing the NEPHRO CRRT registration trial by the end of the year. This is a reduction from the $17 million to $19 million range previously provided.

Conference Call and Webcast Information

Talphera will hold a conference call and webcast at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time 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 32530. 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 **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 there will be six new potentially high-enrolling sites activated during the third quarter, that the NEPHRO study enrollment rates will continue, and additional study sites will be activated on a timely basis allowing the study to be completed by the end of 2025; the potential of nafamostat to address unmet needs in anticoagulation of the extracorporeal circuit, and potential FDA approval of the nafamostat product candidate; and Talphera's expected cash operating expenses will be in the $16 million to $17 million range for 2025. 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	
	2025	**2024**	**2025**	**2024**
Statement of Operations Data				
Revenue	$ -	$ -	$ 27	$ -
			-	-
Operating costs and expenses:				
Research and development [1]	1,500	1,909	2,669	3,342
Selling, general and administrative [1]	2,193	2,361	3,967	5,165
Total operating costs and expenses	3,693	4,270	6,636	8,507
Loss from operations	(3,693)	(4,270)	(6,609)	(8,507)
			-	-
Other income, net:				
Interest income and other income, net	83	201	152	421
Gain on sale of future payments	-	-	-	1,246

Gain (loss) on change in fair value of warrant liability	121	455	302	(547)
Non-cash interest expense on liability related to sale of future payments	-	(213)	-	(394)
Total other income, net	204	443	454	726
Net loss from continuing operations	(3,489)	(3,827)	(6,155)	(7,781)
Net income from discontinued operations	-	-	73	-
Net loss	$ (3,489)	$ (3,827)	$ (6,082)	$ (7,781)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.10)	$ (0.15)	$ (0.20)	$ (0.31)
Basic and diluted, discontinued operations	$ -	$ -	$ 0.00	$ -
Basic and diluted loss per share	$ (0.10)	$ (0.15)	$ (0.20)	$ (0.31)
Shares used in computing net loss per share of common stock, basic and diluted	34,530	26,202	30,422	25,462

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

Research and development	$ 55	$ 85	$ 132	$ 192
Selling, general and administrative	111	138	230	333
Total	$ 166	$ 223	$ 362	$ 525

Selected Balance Sheet Data
(in thousands)

	June 30, 2025	December 31, 2024[1]
	(Unaudited)	(Unaudited)
Cash, cash equivalents and investments	$ 6,791	$ 8,863
Total assets	16,515	18,236
Total liabilities	9,888	10,235
Total stockholders' equity	6,627	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 June 30 (unaudited)		Six Months Ended June 30 (unaudited)	
	2025	**2024**	**2025**	**2024**
Operating expenses (GAAP):				
Research and development	$ 1,500	$ 1,909	$ 2,669	$ 3,342
Selling, general and administrative	2,193	2,361	3,967	5,165
Total operating expenses	3,693	4,270	6,636	8,507
Less stock-based compensation expense	166	223	362	525
Operating expenses (non-GAAP)	$ 3,527	$ 4,047	$ 6,274	$ 7,982

View original content to download multimedia:https://www.prnewswire.com/news-releases/talphera-announces-second-quarter-2025-financial-

results-and-provides-corporate-update-302530470.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