Talphera Announces Third Quarter 2025 Financial Results and Provides Corporate Update

Nov 12, 2025

Closed $17 million first tranche financing led by a strategic investment from CorMedix, Inc.

Cash and investments at September 30, 2025 were $21.3 million; combined with conditional future tranches of previous financings, expect sufficient cash through a potential PMA approval of Niyad in late 2026

5 of the 9 target profile clinical sites are now activated; completion of NEPHRO study expected in H1 2026

Conference call and webcast to be held Wednesday, November 12, 2025 at 4:30 pm ET

SAN MATEO, Calif., Nov. 12, 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 third quarter 2025 financial results and provided a corporate update.

"The financing closed in September, led by a strategic investment from CorMedix, combined with future conditional tranches, is expected to provide us sufficient capital through at least a Niyad PMA approval anticipated in 2026. Their investment, along with investment from existing and new financial investors, further validates the attractiveness of the Niyad market opportunity," stated Vince Angotti CEO of Talphera. "In addition, we're excited about the high quality and skilled execution of the NEPHRO study sites. Importantly, we have received consistent feedback from the principal investigators conveying eagerness for nafamostat to be available as their preferred alternative to current CRRT anticoagulants. The positive enrollment momentum in the NEPHRO clinical study has continued and we look forward to the recently activated sites and the remaining four planned sites to further accelerate the enrollment rate to complete the study in the first half of 2026."

Third Quarter 2025 and Recent Highlights

- Five target profile clinical study sites are actively enrolling patients with four additional target profile sites expected in the fourth quarter of this year.
- In September 2025, Talphera announced the closing of the first tranche of $17 million of a two-tranche private placement financing for up to $29 million. The second closing will occur if Talphera's stock price trades at or above $0.6875 for five consecutive days following the announcement of the achievement of the primary endpoint in the NEPHRO CRRT study. These conditions may be waived by the investors at any time. The financing was led by CorMedix, Inc. (Nasdaq: CRMD) and supported by existing investors, Nantahala Capital, Rosalind Advisors, and Rock Springs Capital, and includes several new institutional investors.
- In September 2025, in connection with its equity investment, Talphera granted CorMedix the right to nominate one member to Talphera's board of directors and the exclusive right of first negotiation for a potential acquisition of the Company with a 60-day exclusive negotiation period following completion and announcement of its Phase 3 study results for Niyad. In October 2025, Talphera appointed Joseph Todisco, CEO of CorMedix, to its board of directors.
- 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.

Third Quarter 2025 Financial Information

- The cash and investments balance was $21.3 million as of September 30, 2025.
- Combined R&D and SG&A expenses for the third quarter of 2025 totaled $3.4 million compared to $3.7 million for the third quarter of 2024. Excluding non-cash stock-based compensation expense, these amounts were $3.3 million for the third quarter of 2025, compared to $3.5 million for the third quarter of 2024. The decrease in combined R&D and SG&A expenses in the third quarter of 2025 was primarily due to reductions in personnel expense and other research and development and selling, general and administrative expenses.
- For the third quarter of 2025, the Company recognized net loss from continuing operations of $4.4 million, as compared to net loss of $3.4 million for the third quarter of 2024, largely due to an increase in the fair value of the Company's warrant liability partially offset by reductions in personnel expense in 2025. 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 third quarter of 2025 or 2024.
- Net loss attributable to common shareholders for the third quarter of 2025 was $4.4 million, or $0.11 per basic and diluted share, compared to a net loss of $3.4 million, or $0.13 per basic and diluted share, for the third 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 $14 million to $15 million in 2025, which includes the expenses related to advancing the NEPHRO CRRT registration trial. This is a reduction from the $16 million to $17 million range previously provided, with the difference expected to be realized in the first quarter of 2026.

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 08207. 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 of study completion in H1 2026, that the current cash balance, combined with conditional future tranches from previous financings, will be sufficient cash through a potential PMA approval of Niyad in late 2026; that there will be four new target profile sites activated during the fourth quarter of 2025; that recently activated sites and the remaining four planned sites are expected to further accelerate the enrollment rate to complete the study enrollment in the first half of 2026; 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 H1 2026; 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 $14 million to $15 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 September 30		Nine Months Ended September 30	
	2025	2024	2025	2024
Statement of Operations Data				
Revenue	$ 1	$ -	$ 28	$ -
Operating costs and expenses:				
Research and development [1]	1,803	2,053	4,472	5,395

Selling, general and administrative [1]	1,620	1,696	5,587	6,861
Total operating costs and expenses	3,423	3,749	10,059	12,256
Loss from operations	(3,422)	(3,749)	(10,031)	(12,256)
Other income, net:				
Interest income and other income, net	81	155	233	576
Gain on sale of future payments	-	-	-	1,246
(Loss) gain on change in fair value of warrant liability	(1,095)	241	(793)	(306)
Non-cash interest expense on liability related to sale of future payments	-	-	-	(394)
Total other income, net	(1,014)	396	(560)	1,122
Net loss from continuing operations	(4,436)	(3,353)	(10,591)	(11,134)
Net income from discontinued operations	-	-	73	-
Net loss	$ (4,436)	$ (3,353)	$ (10,518)	$ (11,134)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.11)	$ (0.13)	$ (0.31)	$ (0.43)
Basic and diluted, discontinued operations	$ -	$ -	$ -	$ -
Basic and diluted loss per share	$ (0.11)	$ (0.13)	$ (0.31)	$ (0.43)
Shares used in computing net loss per share of common stock, basic and diluted	41,454	26,213	34,140	25,714
(1) Includes the following non-cash stock-based compensation expense:				
Research and development	$ 57	$ 92	$ 189	$ 284
Selling, general and administrative	95	142	325	475
Total	$ 152	$ 234	$ 514	$ 759

Selected Balance Sheet Data
(in thousands)

	September 30, 2025 (Unaudited)	December 31, 2024 [1] (Unaudited)
Cash, cash equivalents and investments	$ 21,289	$ 8,863
Total assets	30,742	18,236
Total liabilities	11,565	10,235
Total stockholders' equity	19,177	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 September 30 (unaudited)		Nine Months Ended September 30 (unaudited)	
	2025	**2024**	**2025**	**2024**
Operating expenses (GAAP):				
Research and development	$ 1,803	$ 2,053	$ 4,472	$ 5,395
Selling, general and administrative	1,620	1,696	5,587	6,861
Total operating expenses	3,423	3,749	10,059	12,256
Less stock-based compensation expense	152	234	514	759
Operating expenses (non-GAAP)	$ 3,271	$ 3,515	$ 9,545	$ 11,497

View original content to download multimedia:https://www.prnewswire.com/news-releases/talphera-announces-third-quarter-2025-financial-results-and-provides-corporate-update-302613486.html

SOURCE Talphera, Inc.

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