



Talpera Announces First Quarter 2025 Financial Results and Provides Corporate Update

May 14, 2025

Cash and investments at March 31, 2025, as adjusted to include the proceeds from the first tranche of the private placement financing which closed on April 2, 2025, were \$9.8 million

Three new clinical study sites activated and screening patients thus far in 2025, with five additional sites expected by mid-year, for a total of 13

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

SAN MATEO, Calif., May 14, 2025 /PRNewswire/ -- Talpera, Inc. (Nasdaq: TLPH), ("Talpera"), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced first quarter 2025 financial results and provided a corporate update.

"We remain on track with new study site activation, including three institutions already activated and beginning to screen patients in 2025, and five new potentially high-enrolling sites by mid-year. The new target profile of our clinical study sites has proven beneficial as engagement with the principal investigators and activity at the sites is much higher than with the legacy sites with which we first initiated the study," stated Vince Angotti, CEO of Talpera. "We believe that the increased engagement from the new sites, including those expected to come on board in the coming months, will allow us to complete the 70-patient study by the end of the year. We expect our next enrollment update to occur when we enroll 17 patients, which is the milestone for closing the second tranche of our recent financing. Our confidence in the need for this product candidate continues to grow as we introduce more physicians to the Niyad clinical profile and NEPHRO study," continued Angotti.

First Quarter 2025 and Recent Highlights

- In March 2025, the Company announced it received approval from the U.S. Food and Drug Administration (FDA), on its Prior Approval Supplement (PAS) requesting a reduction in the number of patients in the NEPHRO CRRT clinical study from 166 in the original study protocol to 70. With 70 patients, the primary endpoint is powered at 90%. In January 2025, the agency also agreed to two other changes to broaden the clinical study inclusion criteria which allow the Company to enroll patients already on continuous renal replacement therapy (CRRT) beyond 48 hours, as well as heparin-tolerant patients at certain institutions.
- In March 2025, Talpera announced the agreement for a financing of up to \$14.8 million, including two committed tranches upon achievement of 25% and 50% enrollment and Talpera's stock price trades at a price at or above \$0.7325 for five consecutive days following the announcement of achieving the enrollment milestones. The financing was led by existing investors, Nantahala Capital and Rosalind Advisors, and includes a member of management. The first tranche of this financing amounting to \$4.4 million in net proceeds closed on April 2, 2025.

First Quarter 2025 Financial Information

- The cash and cash equivalents balance was \$5.4 million as of March 31, 2025.
- Combined R&D and SG&A expenses for the first quarter of 2025 totaled \$2.9 million compared to \$4.2 million for the first quarter of 2024. Excluding non-cash stock-based compensation expense, these amounts were \$2.7 million for the first quarter of 2025, compared to \$3.9 million for the first quarter of 2024. The decrease in combined R&D and SG&A expenses in the first quarter of 2025 was primarily due to reductions in personnel expense and other general and administrative expenses.
- For the first quarter of 2025, the Company recognized net loss from continuing operations of \$2.7 million, as compared to net loss of \$4.0 million for the first 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. Net income from discontinued operations was \$0.1 million in the first quarter of 2025.
- Net loss attributable to common shareholders for the first quarter of 2025 was \$2.6 million, or \$0.10 per basic and diluted share, compared to a net loss of \$4.0 million, or \$0.16 per basic and diluted share, for the first 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 \$17 million to \$19 million in 2025, which includes the expenses related to executing and completing the NEPHRO CRRT registration trial before the end of the year.

Conference Call and Webcast Information

Talpera 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 58894. The webcast can be accessed [here](#) or by visiting the Investors section of the Company's website at www.talpera.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 (Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy) 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 five new potentially high-enrolling sites activated by mid-year, that the NEPHRO study enrollment rates will increase, and additional study sites will be activated 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; Talphera's expectation that the committed capital from the private placement financing, upon completion of certain milestones and meeting certain closing conditions, should provide sufficient capital to fund the completion of the NEPHRO study, expected by the end of 2025; Talphera's expected cash operating expenses will be in the \$17 million to \$19 million range for 2025; and Talphera's ability to successfully meet the enrollment goals and minimum stock price to satisfy the requirements of the two additional committed private placement financing tranches. 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	
	March 31	
	2025	2024
Statement of Operations Data		
Revenue	\$ 27	\$ -
Operating costs and expenses:		
Research and development ⁽¹⁾	1,169	1,433
Selling, general and administrative ⁽¹⁾	1,774	2,804
Total operating costs and expenses	2,943	4,237
Loss from operations	(2,916)	(4,237)
Other income, net:		

Interest income and other income, net	69	220
Gain on sale of future payments	-	1,246
Gain (loss) on change in fair value of warrant liability	181	(1,002)
Non-cash interest expense on liability related to sale of future payments	-	(181)
Total other income, net	250	283
Net loss from continuing operations	(2,666)	(3,954)
Net income from discontinued operations	73	-
Net loss	<u>\$ (2,593)</u>	<u>\$ (3,954)</u>

Net loss per share attributable to stockholders:

Basic and diluted, continuing operations	<u>\$ (0.10)</u>	<u>\$ (0.16)</u>
Basic and diluted, discontinued operations	<u>\$ 0.00</u>	<u>\$ -</u>
Basic and diluted loss per share	<u>\$ (0.10)</u>	<u>\$ (0.16)</u>
Shares used in computing net loss per share of common stock, basic and diluted	<u>26,268</u>	<u>24,722</u>

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

Research and development	\$ 77	\$ 107
Selling, general and administrative	119	195
Total	<u>\$ 196</u>	<u>\$ 302</u>

Selected Balance Sheet Data
(in thousands)

	March 31, 2025	December 31, 2024⁽¹⁾
	(Unaudited)	(Unaudited)
Cash, cash equivalents and investments	\$ 5,388	\$ 8,863
Total assets	14,995	18,236
Total liabilities	9,396	10,235
Total stockholders' equity	5,599	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	
	March 31	
	(unaudited)	
	2025	2024
Operating expenses (GAAP):		
Research and development	\$ 1,169	\$ 1,433
Selling, general and administrative	1,774	2,804
Total operating expenses	2,943	4,237
Less stock-based compensation expense	196	302
Operating expenses (non-GAAP)	<u>\$ 2,747</u>	<u>\$ 3,935</u>



SOURCE Talpera, Inc.

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