Talphera Announces Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

Mar 31, 2025

The U.S. Food and Drug Administration (FDA) agreed to reduce the number of patients in the NEPHRO CRRT study from 166 to 70

Talphera expects the registrational NEPHRO CRRT study to be completed by the end of 2025

Cash and investments at December 31, 2024 of $8.9 million, together with the private placement financing recently announced of up to $14.8 million, expected to provide capital through target completion of the NEPHRO study in the fourth quarter of 2025

Conference call and webcast to be held Monday, March 31, 2025 at 4:30 pm ET

SAN MATEO, Calif., March 31, 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 fourth quarter and full year 2024 financial results and provided a corporate update.

"The recent announcements of the FDA's approval to reduce the study size to 70 patients, the private placement financing, and FDA-agreed study protocol changes, provide strong momentum to support the NEPHRO CRRT study execution," stated Vince Angotti, Chief Executive Officer of Talphera. "These developments, coupled with the addition of new sites with higher enrollment potential, two of which have just started screening patients with six more sites expected in the first half of this year, support our belief that we will complete the study by the end of 2025. In addition, clinicians' continued enthusiasm for Niyad's profile reinforces our confidence in its potential to fill a significant unmet need in the CRRT market," continued Angotti.

Fourth Quarter 2024 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, Talphera announced the agreement for a financing of up to $14.8 million, including two committed tranches following achievement of 25% and 50% enrollment, respectively, and the Talphera stock price trades at a price of $0.7325 for five consecutive days after 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.

Fourth Quarter 2024 Financial Information

- The cash and cash equivalents balance was $8.9 million as of December 31, 2024.
- Combined R&D and SG&A expenses for the fourth quarter of 2024 totaled $3.0 million and compared to $4.6 million for the fourth quarter of 2023. Excluding non-cash stock-based compensation expense, these amounts were $2.8 million for the fourth quarter of 2024, compared to $4.3 million for the fourth quarter of 2023. The decrease in combined R&D and SG&A expenses in the fourth quarter of 2024 was primarily due to reductions in personnel expense and other general and administrative expenses.
- For the fourth quarter of 2024, the Company recognized net loss from continuing operations of $1.9 million, as compared to net loss of $4.5 million for the fourth quarter of 2023, largely due to the change in fair value of the Company's warrant liability. 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 fourth quarter of 2024.
- Net loss attributable to common shareholders for the fourth quarter of 2024 was $1.9 million, or $0.07 per basic and diluted share, compared to a net loss of $4.5 million, or $0.25 per basic and diluted share, for the fourth quarter of 2023.

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 $18 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

Talphera will hold a conference call and webcast at 4:30 p.m. Eastern Standard Time/1:30 p.m. Pacific Standard 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 11814.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 the NEPHRO study enrollment rates will increase, additional study sites will be activated allowing the study to be completed by the end of 2025, that nafamostat, if approved, will potentially avoid the risks of systemic anticoagulation, the potential of nafamostat to address unmet needs in anticoagulation of the extracorporeal circuit, the potential advantage of having Breakthrough Device Designation, 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; 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 December 31		Year Ended December 31	
	2024	**2023**	**2024**	**2023**
Statement of Operations Data				
Revenue	$ -	$ 281	$ -	$ 651
Operating costs and expenses:				
Research and development [1]	1,323	1,769	6,718	5,546
Selling, general and administrative [1]	1,673	2,795	8,534	11,994
Total operating costs and expenses	2,996	4,564	15,252	17,540
Loss from operations	(2,996)	(4,283)	(15,252)	(16,889)

Other income, net:				
Interest expense	-	-	-	(134)
Interest income and other income, net	103	171	679	1,416
Gain on sale of future payments	-	-	1,246	-
Gain (loss) on change in fair value of warrant liability	1,023	(398)	717	5,320
Non-cash interest expense on liability related to sale of future payments	-	-	(394)	-
Total other income, net	1,126	(227)	2,248	6,602
Net loss before income taxes	(1,870)	(4,510)	(13,004)	(10,287)
Benefit for income taxes	-	5	-	-
Net loss from continuing operations	(1,870)	(4,505)	(13,004)	(10,287)
Net loss from discontinued operations	-	(12)	-	(8,110)
Net loss	$ (1,870)	$ (4,517)	$ (13,004)	$ (18,397)
Net loss per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.07)	$ (0.25)	$ (0.50)	$ (0.72)
Basic and diluted, discontinued operations	$ -	$ (0.00)	$ -	$ (0.57)
Basic and diluted loss per share	$ (0.07)	$ (0.25)	$ (0.50)	$ (1.29)
Shares used in computing net loss per share of common stock, basic and diluted	26,238	18,369	25,846	14,264
(1) Includes the following non-cash stock-based compensation expense:				
Research and development	$ 91	$ 115	$ 375	$ 498
Selling, general and administrative	139	196	614	1,212
Discontinued operations	-	-	-	19
Total	$ 230	$ 311	$ 989	$ 1,729

Selected Balance Sheet Data
(in thousands)

	December 31, 2024 (Unaudited)	December 31, 2023[1] (Unaudited)
Cash, cash equivalents and investments	$ 8,863	$ 9,381
Total assets	18,236	20,395
Total liabilities	10,235	6,290
Total stockholders' equity	8,001	14,105

[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, 2023.

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less stock-based compensation expense)

	Three Months Ended December 31		Year Ended December 31	
	2024	**2023**	**2024**	**2023**
Operating expenses (GAAP):				
Research and development	$ 1,323	$ 1,769	$ 6,718	$ 5,546
Selling, general and administrative	1,673	2,795	8,534	11,994
Total operating expenses	2,996	4,564	15,252	17,540
Less stock-based compensation expense	230	311	989	1,710
Operating expenses (non-GAAP)	$ 2,766	$ 4,253	$ 14,263	$ 15,830

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