Talphera Announces Third Quarter 2024 Financial Results and Provides Corporate Update

Nov 13, 2024

Five sites actively screening with multiple patients having completed the study; two additional institutions expected to begin screening in the fourth quarter totaling seven active sites

Cash and investments at September 30, 2024 of $11.1 million

Conference call and webcast to be held Wednesday, November 13, 2024 at 4:30 pm ET

SAN MATEO, Calif., Nov. 13, 2024 /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 2024 financial results and provided a corporate update.

"Our NEPHRO CRRT study has gained momentum, with activated study sites now screening patients and two additional sites to begin screening in the fourth quarter. We're actively engaged with new high-volume sites we expect to further contribute to enrollment rates in the first half of 2025. While we are not providing specific guidance on the study completion date, with execution of our plan to improve enrollment rates and activation of additional study sites, we anticipate the study to be completed next year," stated Vince Angotti, Talphera Chief Executive Officer. "As a reminder, this is not a prolonged study as the primary endpoint is measured at 24 hours with a patient completing the study at 72 hours," continued Angotti.

Dr. Shakil Aslam, Talphera Chief Medical Officer, added, "I remain convinced that nafamostat, if approved, will provide the first FDA-approved regional anticoagulant for CRRT, potentially avoiding the risks of systemic anticoagulation that occurs with heparin. After engagement and discussion with numerous clinicians and the NEPHRO investigators, we have identified opportunities to further improve patient screening and enrollment for a timely completion of the study."

Third quarter 2024 and recent highlights

- The first patient was enrolled in the NEPHRO CRRT study in August 2024.
- Five clinical sites have been activated and are screening patients, with multiple patients now having completed the study. Two additional large-volume clinical sites are expected to be screening patients in the fourth quarter. The NEPHRO CRRT study will enroll 166 patients undergoing continuous renal replacement therapy (CRRT) at up to 14 clinical sites across the United States. The primary endpoint of the study is the mean post-filter activated clotting time for circuits infused with nafamostat compared to placebo over the first 24 hours.
- In October, we met with several physicians, nurses and NEPHRO CRRT study principal investigators at the American Society of Nephrology's Kidney Week 2024 in San Diego, confirming dissatisfaction with the current anticoagulants and validating the target product profile of nafamostat and its potential as a much-needed alternative anticoagulant for CRRT.

Third Quarter 2024 Financial Information

- The cash, cash equivalents and investments balance was $11.1 million as of September 30, 2024.
- Combined R&D and SG&A expenses for the third quarter of 2024 totaled $3.7 million compared to $3.4 million for the third quarter of 2023. Excluding non-cash stock-based compensation expense, these amounts were $3.5 million for the third quarter of 2024, compared to $3.0 million for the third quarter of 2023. The increase in combined R&D and SG&A expenses in the third quarter of 2024 was primarily due to an increase in costs associated with the NEPHRO study, partially offset by lower SG&A expenses.
- For the third quarter of 2024, the Company recognized net loss from continuing operations of $3.4 million, as compared to net loss of $1.4 million for the third 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 third quarter of 2024.
- Net loss attributable to common shareholders for the third quarter of 2024 was $3.4 million, or $0.13 per basic and diluted share, compared to a net loss of $1.4 million, or $0.08 per basic and diluted share, for the third quarter of 2023.

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 89949. 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 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 166 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 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 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	
	2024	2023	2024	2023
Statement of Operations Data				
Revenue	$ -	$ 117	$ -	$ 370
Operating costs and expenses:				
Research and development [1]	2,053	1,178	5,395	3,777
Selling, general and administrative [1]	1,696	2,248	6,861	9,199
Total operating costs and expenses	3,749	3,426	12,256	12,976
Loss from operations	(3,749)	(3,309)	(12,256)	(12,606)
Other income, net:				
Interest expense	-	-	-	(134)
Interest income and other income, net	155	187	576	1,245
Gain on sale of future payments	-	-	1,246	-
Gain (loss) on change in fair value of warrant liability	241	1,706	(306)	5,718
Non-cash interest expense on liability related to sale of future payments	-	-	(394)	-
Total other income, net	396	1,893	1,122	6,829
Net loss before income taxes	(3,353)	(1,416)	(11,134)	(5,777)

Provision for income taxes	-	(2)	-	(5)
Net loss from continuing operations	(3,353)	(1,418)	(11,134)	(5,782)
Net income (loss) from discontinued operations	-	61	-	(8,098)
Net loss	$ (3,353)	$ (1,357)	$ (11,134)	$ (13,880)
Net (loss) income per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.13)	$ (0.08)	$ (0.43)	$ (0.45)
Basic and diluted, discontinued operations	$ -	$ 0.00	$ -	$ (0.63)
Basic and diluted loss per share	$ (0.13)	$ (0.08)	$ (0.43)	$ (1.08)
Shares used in computing net loss per share of common stock, basic and diluted	26,213	16,758	25,714	12,880
(1) Includes the following non-cash stock-based compensation expense:				
Research and development	$ 92	$ 210	$ 284	$ 383
Selling, general and administrative	142	168	475	1,016
Discontinued operations	-	-	-	19
Total	$ 234	$ 378	$ 759	$ 1,418

Selected Balance Sheet Data
(in thousands)

	September 30, 2024 (Unaudited)	December 31, 2023[1] (Unaudited)
Cash, cash equivalents and investments	$ 11,117	$ 9,381
Total assets	21,014	20,395
Total liabilities	11,373	6,290
Total stockholders' equity	9,641	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 September 30		Nine Months Ended September 30	
	2024	**2023**	**2024**	**2023**
Operating expenses (GAAP):				
Research and development	$ 2,053	$ 1,178	$ 5,395	$ 3,777
Selling, general and administrative	1,696	2,248	6,861	9,199
Total operating expenses	3,749	3,426	12,256	12,976
Less stock-based compensation expense	234	378	759	1,399
Operating expenses (non-GAAP)	$ 3,515	$ 3,048	$ 11,497	$ 11,577

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