Talphera Announces First Quarter 2024 Financial Results and Provides Corporate Update

May 14, 2024

First patients at multiple sites are expected to be enrolled in the NEPHRO CRRT registrational study in Q2 2024

Dr. Shakil Aslam, an expert in renal diseases, including acute kidney injury, joins Talphera as Chief Development Officer

Cash and investments at March 31, 2024 of $18.6 million

Conference call and webcast to be held Tuesday, May 14, 2024 at 4:30 pm ET

SAN MATEO, Calif., May 14, 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 first quarter 2024 financial results and provided a corporate update.

"We are eager to have the first patient enrolled in the NEPHRO study so we can complete this pivotal trial and demonstrate the efficacy and safety of this unique anticoagulant. We have finalized clinical trial agreement terms with five large academic institutions and are awaiting these sites to complete their final internal start-up activities before patients are enrolled," stated Vince Angotti, CEO of Talphera. "While the initial site activation has taken longer than expected, based on our ongoing discussions with the principal investigators, they are eager to get started and expect the trial will complete quickly given the primary endpoint is measured at 24 hours. As a result of the initial delays, we expect that our previous guidance of having top-line data available by September 30 will be revised. Once patients begin enrolling, we plan to provide an updated expected study completion date. Finally, the addition of Dr. Aslam to Talphera will provide significant nephrology expertise to the team and further support the development and commercial preparation of Niyad," continued Angotti.

First quarter 2024 and recent highlights

- In January of this year, the Company announced a corporate rebranding, changing its name from AcelRx Pharmaceuticals, Inc. to Talphera, Inc. The decision to rebrand was made following the divestment of assets indicated for acute pain and the shift in focus to its new lead asset, Niyad, reinforcing the Company's vision of developing and commercializing products to support healthcare providers in optimizing outcomes in medically supervised settings. Talphera began trading on the Nasdaq Global Market under the ticker symbol "TLPH" on January 10, 2024.
- In January 2024, Talphera announced a total of $26 million in committed capital, including (i) $8 million from a partial monetization of DSUVIA royalties and milestones with Xoma Royalty, and (ii) $18 million in total equity from two existing investors structured as $6 million of equity issued at the first closing, $10 million of committed capital upon the announcement of positive NEPHRO registration trial data, and an additional $2 million commitment if Talphera stock trades above a specified price following that announcement.
- Clinical trial agreements with five large academic institutions have been finalized, and we await completion of their final internal start-up activities so these sites can begin enrolling patients. First patients are expected to be enrolled at multiple sites in the second quarter of this year.
- Dr. Shakil Aslam will join Talphera effective May 20, 2024 as Chief Development Officer. Dr. Aslam has over 20 years of clinical and research experience across a broad therapeutic range including renal and vascular disease and acute kidney injury. He joins Talphera from BioCryst Pharmaceuticals where he was the Vice President, Clinical Development, Nephrology and Rare Diseases. Dr. Aslam previously held roles at Angion Biomedica, Fresenius Medical Care and Amgen and was an assistant professor at Georgetown University hospital for eleven years with a focus on acute and chronic kidney disease, hypertension, renal transplantation, and other nephrological diseases.

First Quarter 2024 Financial Information

- The cash and cash equivalents balance was $18.6 million as of March 31, 2024.
- Combined R&D and SG&A expenses for the first quarter of 2024 totaled $4.2 million compared to $5.3 million for the first quarter of 2023. Excluding non-cash stock-based compensation expense, these amounts were $3.9 million for the first quarter of 2024, compared to $4.8 million for the first quarter of 2023. The decrease in combined R&D and SG&A expenses in the first quarter of 2024 was primarily due to reduced headcount attributed to the divestment of DSUVIA.
- For the first quarter of 2024, the Company recognized net loss from continuing operations of $4.0 million, as compared to net income from continuing operations of $0.1 million for the first 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.
- Net loss attributable to common shareholders for the first quarter of 2024 was $4.0 million, or $0.16 per basic and diluted share, compared to a net loss of $8.2 million, or $0.75 per basic and diluted share, for the first quarter of 2023.

Conference Call and Webcast Information

Talphera will hold a conference call and webcast at 4:30 p.m. Eastern Daylight Time/1:30 p.m. Pacific Daylight 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 79169.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). Talphera is also developing two pre-filled syringes in-licensed from its partner Aguettant: Fedsyra™, a pre-filled ephedrine syringe, and PFS-02, a pre-filled phenylephrine syringe.

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™, the NEPHRO CRRT (Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy) study has received central Institutional Review Board (IRB) approval. 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 10 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," "finalize," "may," "if," "intends," "plans," "potential," "projected," "will," or the negative of these words or other comparable terminology, and include; Talphera's expectation of first patient enrollment in its NEPHRO CRRT registrational trial in Q2 2024; Talphera's plan to provide an estimated study completion date of the NEPHRO study after the study begins enrolling; and Talphera's expectation that the NEPHRO study will complete quickly. 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 confirm any safety, potency or other product characteristics described or assumed in this press release; (ii) Talphera's developmental product candidates may not be beneficial to patients 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	
	2024	**2023**
Statement of Operations Data		
Operating costs and expenses:		
Research and development [1]	$ 1,433	$ 1,047
Selling, general and administrative [1]	2,804	4,281
Total operating costs and expenses	4,237	5,328
Loss from operations	(4,237)	(5,328)
Other income:		
Interest expense	-	(119)
Interest income and other income, net	220	200
Gain on sale of future payments	1,246	-
Change in fair value of warrant liability	(1,002)	5,311

Non-cash interest expense on liability related to sale of future payments	(181)	-
Total other income	283	5,392
Net (loss) income from continuing operations	(3,954)	64
Net loss from discontinued operations	-	(8,216)
Net loss	$ (3,954)	$ (8,152)
Net (loss) income per share attributable to stockholders:		
Basic and diluted, continuing operations	$ (0.16)	$ -
Basic and diluted, discontinued operations	$ -	$ (0.75)
Basic and diluted loss per share	$ (0.16)	$ (0.75)
Shares used in computing net (loss) income per share of common stock, basic and diluted	24,722	10,894

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

Research and development	$ 107	$ 93
Selling, general and administrative	195	457
Discontinued operations	-	19
Total	$ 302	$ 569

Selected Balance Sheet Data
(in thousands)

	March 31, 2024	December 31, 2023[1]
	(Unaudited)	
Cash, cash equivalents and investments	$ 18,584	$ 9,381
Total assets	28,772	20,395
Total liabilities	12,438	6,290
Total stockholders' equity	16,334	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 March 31	
	2024	**2023**
Operating expenses (GAAP):		
Research and development	$ 1,433	$ 1,047
Selling, general and administrative	2,804	4,281
Total operating expenses	4,237	5,328
Less stock-based compensation expense	302	550
Operating expenses (non-GAAP)	$ 3,935	$ 4,778

View original content to download multimedia:https://www.prnewswire.com/news-releases/talphera-announces-first-quarter-2024-financial-results-and-provides-corporate-update-302145300.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, Chris Calabrese, 917-680-5608, ccalabrese@lifesciadvisors.com