UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 12, 2024

TALPHERA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

1850 Gateway Drive, Suite 175
San Mateo, CA 94404
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 216-3500**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	TLPH	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On August 14, 2024, Talphera, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 2024 and providing a corporate update (the "Release"). A copy of the Release is furnished herewith as Exhibit 99.1.

The information contained in this Item 2.02 and in Exhibit 99.1 shall be deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 12, 2024, Pamela P. Palmer, MD, PhD, the Company's Chief Medical Officer and co-founder, notified the Company that she plans to retire and resign from the Company effective October 1, 2024. Upon Dr. Palmer's retirement, Dr. Shakil Aslam, currently the Company's Chief Development Officer, will assume the position of the Company's Chief Medical Officer. Dr. Palmer will consult with the Company to ensure a seamless transition. Dr. Palmer's decision to resign is not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated August 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 14, 2024

TALPHERA, INC.

By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

TALPHERA

Talphera Announces Second Quarter 2024 Financial Results and Provides Corporate Update

NEPHRO CRRT study patient screening has initiated at multiple clinical sites

The safety and effectiveness of nafamostat is being assessed in the NEPHRO CRRT registrational study in 166 patients at up to 14 clinical sites

Cash and investments at June 30, 2024 of $14.0 million

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

SAN MATEO, Calif., August 14, 2024 – 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 second quarter 2024 financial results and provided a corporate update.

"We're excited to have initiated the screening of patients at multiple clinical sites in the NEPHRO CRRT registrational study. We now have finalized clinical trial agreement terms with eight large academic institutions including our potentially highest enrolling sites. We have also received FDA approval to increase the maximum number of study sites from 10 to 14 which we believe will help expedite completion of the study," stated Vince Angotti, CEO of Talphera. "The NEPHRO study should be enrolled and completed efficiently given the measurement of the primary endpoint is at 24 hours, with patients completing the study after 72 hours. In addition, having Breakthrough Device Designation from the FDA potentially provides an advantage for a timely approval of the product candidate next year. Nafamostat has the potential to address known disadvantages of currently available U.S. products for anticoagulation of the extracorporeal circuit and has been used, as a standard of care, in Japan and South Korea for over 30 years. We're looking forward to making nafamostat available to healthcare providers in the United States, if approved," continued Angotti.

Dr. Shakil Aslam, Talphera's Chief Development Officer, has been leading the NEPHRO CRRT study since joining the Company. Dr. Aslam's expertise in nephrology and his 20 years of experience in academia and drug and device development has already proven to be an asset. Oversight of the NEPHRO study transitioned to Dr. Aslam from Dr. Palmer, Talphera's Chief Medical Officer, who, after nearly two decades in this role, will be retiring in October. Upon Dr. Palmer's retirement, Dr. Aslam will succeed her as Talphera's Chief Medical Officer and Dr. Palmer will continue as a consultant to the Company until completion of the NEPHRO study.

“On behalf of the Board and the entire organization, I want to thank Pam for her leadership and dedication over her many years of service with the Company. We wish her all the best with her well-deserved retirement after co-founding Talphera and serving on the Board and as Chief Medical Officer for the last 19 years. Pam has been the scientific and medical force behind the Company, successfully achieving a U.S. drug approval and two European drug approvals. It has been a privilege to work with Dr. Palmer over the past seven years and I am grateful that Pam has agreed to remain as a consultant until the NEPHRO study has been completed. Additionally, we are delighted to have Dr. Aslam on board. Shakil is already making major contributions to Talphera, including expediting activities with the NEPHRO study,” stated Vince Angotti.

Second quarter 2024 and recent highlights

- Screening has been initiated at multiple clinical sites in the NEPHRO CRRT registrational study. 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 against placebo over the first 24 hours.

- Clinical trial agreement terms with eight large academic institutions have been finalized with the final four site initiation visits of these initial eight institutions scheduled to be completed this month.

- Dr. Shakil Aslam joined 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 joined 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 twelve years with a focus on acute and chronic kidney disease, hypertension, renal transplantation, and other nephrological diseases.

Second Quarter 2024 Financial Information

- The cash, cash equivalents and investments balance was $14.0 million as of June 30, 2024.

- Combined R&D and SG&A expenses for the second quarter of 2024 totaled $4.3 million compared to $4.2 million for the second quarter of 2023. Excluding non-cash stock-based compensation expense, these amounts were $4.0 million for the second quarter of 2024, compared to $3.8 million for the second quarter of 2023. The increase in combined R&D and SG&A expenses in the second quarter of 2024 was primarily due to an increase in costs associated with Niyad development.

- For the second quarter of 2024, the Company recognized net loss from continuing operations of $3.8 million, as compared to net loss of $4.4 million for the second 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 second quarter of 2024.

- Net loss attributable to common shareholders for the second quarter of 2024 was $3.8 million, or $0.15 per basic and diluted share, compared to a net loss of $4.4 million, or $0.40 per basic and diluted share, for the second 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 28132. 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,” “finalize,” “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 will enroll and complete efficiently, the potential of nafamostat to address unmet needs in anticoagulation of the extracorporeal circuit, and 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.

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

###

Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30		Six Months Ended June 30	
	2024	2023	2024	2023
Statement of Operations Data				
Revenue	$ -	$ 253	$ -	$ 253
Operating costs and expenses:				
Research and development [1]	1,909	1,552	3,342	2,599
Selling, general and administrative [1]	2,361	2,670	5,165	6,951
Total operating costs and expenses	4,270	4,222	8,507	9,550
Loss from operations	(4,270)	(3,969)	(8,507)	(9,297)
			-	
Other income:				
Interest expense	-	(15)	-	(134)
Interest income and other income, net	201	858	421	1,058
Gain on sale of future payments	-	-	1,246	-
Change in fair value of warrant liability	455	(1,299)	(547)	4,012
Non-cash interest expense on liability related to sale of future payments	(213)	-	(394)	-
Total other income (expense)	443	(456)	726	4,936
Net loss before income taxes	(3,827)	(4,425)	(7,781)	(4,361)
Provision for income taxes	-	(3)	-	(3)
Net loss from continuing operations	(3,827)	(4,428)	(7,781)	(4,364)
Net income (loss) from discontinued operations	-	57	-	(8,159)
Net loss	$ (3,827)	$ (4,371)	(7,781)	(12,523)
Net (loss) income per share attributable to stockholders:				
Basic and diluted, continuing operations	$ (0.15)	$ (0.41)	$ (0.31)	$ (0.40)
Basic and diluted, discontinued operations	$ -	$ 0.01	$ -	$ (0.75)
Basic and diluted loss per share	$ (0.15)	$ (0.40)	$ (0.31)	$ (1.15)
Shares used in computing net (loss) income per share of common stock, basic and diluted	26,202	10,924	25,462	10,909
			$ -	
(1) Includes the following non-cash stock-based compensation expense:				
			0	
Research and development	$ 85	$ 80	$ 192	$ 173
Selling, general and administrative	138	391	333	848
Discontinued operations	-	-	-	19
Total	$ 223	$ 471	$ 525	$ 1,040

Selected Balance Sheet Data
(in thousands)

	June 30, 2024 (Unaudited)	December 31, 2023[1]
Cash, cash equivalents and investments	$ 14,023	$ 9,381
Total assets	24,856	20,395
Total liabilities	12,126	6,290
Total stockholders' equity	12,730	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 June 30		Twelve Months Ended June 30	
	2024	**2023**	**2024**	**2023**
Operating expenses (GAAP):				
Research and development	$ 1,909	$ 1,552	$ 3,342	$ 2,599
Selling, general and administrative	2,361	2,670	5,165	6,951
Total operating expenses	4,270	4,222	8,507	9,550
Less stock-based compensation expense	223	471	525	1,021
Operating expenses (non-GAAP)	$ 4,047	$ 3,751	$ 7,982	$ 8,529