Talphera Announces $26 Million Capital Commitment Through a Combination of a Non-Dilutive Royalty Monetization and Equity Offering

Jan 18, 2024

The total committed funding is expected to provide sufficient capital to fund Talphera through a potential FDA approval of Niyad™, targeted for the first half of 2025

$16 million of total equity committed with $6 million upfront and $10 million upon the announcement of positive NEPHRO registration trial data

Existing investors, Nantahala Capital and Rosalind Advisors, committed the total equity capital priced at-the-market as defined by Nasdaq rules

$8 million of non-dilutive capital received from XOMA Royalty from the partial monetization of DSUVIA royalties and milestones

Upon XOMA Royalty receiving a specified return, Talphera and XOMA Royalty will share in certain royalties and milestones earned from the sales of DSUVIA

Abhinav Jain from Nantahala Capital Management will join the Talphera Board at closing of the equity offering

SAN MATEO, Calif., Jan. 18, 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 a total of $26 million of committed capital including $8 million from a partial monetization of DSUVIA royalties and milestones, $6 million of equity issued at a first closing, $10 million of committed capital upon the announcement of positive NEPHRO registration trial data, and an additional $2 million if Talphera stock trades above a specified price following the NEPHRO registration trial announcement.

"The combination of the non-dilutive and equity financing transactions is expected to secure our funding through a potential FDA approval of Niyad targeted for the first half of 2025," said Vince Angotti, Talphera Chief Executive Officer. "The strong support from Nantahala and Rosalind demonstrated by the capital committed further enforces our belief in Niyad's market potential and the significance of the recent corporate rebranding to Talphera. We are eager to demonstrate through our pivotal study why Niyad has received Breakthrough Designation from the FDA, and potentially introduce a much-anticipated new alternative to healthcare providers," continued Angotti. "Finally, being able to secure a non-dilutive royalty capital solution from XOMA to focus our resources on Niyad while still being able to participate in the DSUVIA royalty and milestone stream is an ideal transaction for Talphera. While we continue to believe in DSUVIA's long-term potential in the hands of Alora, our priority has shifted to advancing our lead program, Niyad, with the execution of the NEPHRO registration trial and the expected Niyad PMA submission later this year."

The equity offering and commitment

The equity issuance transaction with Nantahala Capital and Rosalind Advisors totals $18 million, with (a) $6 million at the first closing, (b) $10 million at the second closing upon Talphera announcing the achievement of the NEPHRO registration trial's primary endpoint and a statistically significant secondary endpoint of mean post-filter activated clotting time (ACT) composed of measurements made in the first 72 hours (the "Pivotal Trial Milestone"), and (c) an additional $2 million should Talphera stock trade at a price of at least $0.92 per share for 5 days after the announcement of the NEPHRO registration trial data (the "Price Milestone"). At closing, expected on January 19, 2024, Abhinav Jain of Nantahala Capital Management will join Talphera's Board of Directors, further strengthening Talphera's Board.

Talphera will issue 7,792,208 pre-funded warrants in lieu of shares to purchase common stock at a price of $0.769 per share at the first closing of the transaction. The warrants will have an exercise price of $0.001 per share, for a total purchase price per share of common stock of $0.77. Talphera expects to issue 12,987,013 pre-funded warrants in lieu of common stock at a price of $0.769 per share at a second closing upon the achievement of the Pivotal Trial Milestone, and 2,597,403 pre-funded warrants in lieu of common stock at a price of $0.769 per share upon the achievement of the Price Milestone. See below for further details about the equity offering.

In addition, Talphera will amend certain Series A common stock warrants to purchase up to 2,941,178 shares of common stock and certain Series B common stock warrants to purchase up to 2,941,178 shares of common stock previously issued to Nantahala and Rosalind in July 2023, to lower the exercise price of such warrants to $0.77 per share. The total additional capital available to the Company should all outstanding Series A and Series B common stock warrants be exercised is $14.4 million.

The royalty financing transaction

Talphera has completed a partial monetization of its DSUVIA royalties and milestones with XOMA for $8 million. Upon XOMA achieving a specified return, Talphera and XOMA will share equally in the royalties earned on DSUVIA sales to the Department of Defense, and all milestones earned. This transaction was closed on January 12, 2024. The previous sale of DSUVIA to Alora generates a 15% royalty on commercial sales of DSUVIA, 75% royalties on sales of DSUVIA to the Department of Defense and up to $116.5 million in sales-based milestones.

Corporate updates

Talphera expects the committed funding to provide sufficient capital to fund Talphera through a potential approval of Niyad, targeted in the first half of 2025. Talphera expects the top-line data read-out of its NEPHRO registration trial in the third quarter of 2024, with an expected pre-market approval (PMA) application submitted before the end of 2024. Talphera preliminary cash balance at the end of 2023 totaled approximately $9.4 million. 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 $21 million to $23 million in 2024, which includes the initiation and expected completion of the NEPHRO registration trial during the year.

The offer and sale of the securities described above are being offered and sold in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and Regulation D promulgated thereunder, and have not been registered under the Act, or applicable state securities laws. Accordingly, such securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

The Company has agreed to file a registration statement under the Act with the Securities and Exchange Commission (the "SEC"), covering the resale of the shares of common stock to be issued in the private placement and the shares of common stock underlying the pre-funded warrants no later than 15 days following the closing date, and to use reasonable best efforts to have the registration statement declared effective as promptly as practical thereafter, and in any event no later than 90 days following the closing date in the event of a "full review" by the SEC.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation status from the 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 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 investigational device exemption (IDE), as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. 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 and COVID, amongst other potential targets.

Forward-looking statements
This press release contains forward-looking statements based upon Talphera's current expectations. 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 "potential," "potentially," "believe," "expect," "anticipate," "may," "will," "if," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "targeted," "estimates," "sufficient," "benefits," or the negative of these words or other comparable terminology, and include Talphera's statements regarding a potential FDA approval of Niyad targeted for the first half of 2025; Talphera's expectation of the top-line data read out of its NEPHRO registration trial in the third quarter of 2024, with an expected PMA application submitted before the end of 2024; Talphera's expectation that the committed funding will provide sufficient capital to fund Talphera through a potential approval of Niyad, targeted in the first half of 2025; and Talphera's expected cash operating expenses for 2024. The discussion of strategy, plans or intentions may 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 and ongoing commercial business operations; (ii) risks related to the ability of Talphera and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iii) risks related to unexpected variations in market growth and demand for Talphera 's commercial and developmental products and technologies; (iv) risks related to Talphera 's liquidity and its ability to maintain capital resources sufficient to conduct the required clinical studies; (v) Talphera 's ability to retain its listing on the Nasdaq exchange; and (vi) risks relating to Talphera's ability to obtain regulatory approvals for its developmental product candidates. 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.

Non-GAAP Financial Measures
Estimated cash operating expenses for 2024 is a forward-looking non-GAAP financial measure. Talphera does not provide a reconciliation for non-GAAP estimates on a forward-looking basis where it is unable to provide a meaningful calculation or estimate of reconciling items and the information is not available without unreasonable effort. This is due to the inherent difficulty of forecasting the timing or amount non-cash stock-based compensation and other items that would impact the most directly comparable forward-looking U.S. GAAP financial measure that have not yet occurred and cannot be reasonably estimated. Forward-looking non-GAAP financial measures provided without the most directly comparable U.S. GAAP financial measures may vary materially from the corresponding U.S. GAAP financial measures.

Preliminary Financial Information
Talphera's estimate of its cash as of December 31, 2023 is based on management's preliminary, unaudited analysis of Talphera's financial results as of and for year ended December 31, 2023, and is subject to change as a result of the completion of the Company's standard financial and operating closing procedures and customary audit procedures. The Company's independent registered accounting firm has not audited the preliminary financial data discussed in this press release. As a result, the preliminary cash estimate constitutes forward-looking information and is subject to risks and uncertainties, including possible adjustments. Accordingly, investors should not place undue reliance on this preliminary financial data.

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