

**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): March 21, 2022

Terns Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39926
(Commission File Number)

98-1448275
(IRS Employer
Identification No.)

**1065 East Hillsdale Blvd.
Suite 100
Foster City, California**
(Address of Principal Executive Offices)

94404
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 525-5535

N/A

(Former Name or Former Address, if Changed Since Last Report)

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:

- 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, \$0.0001 par value per share	TERN	NASDAQ Global Select 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 8.01 Other Events.

On March 21, 2022, Terns Pharmaceuticals, Inc. (the “Company” or “Terns”) announced top-line results from Part 1 of its Phase 1b AVIATION Trial of TERN-201 in patients with nonalcoholic steatohepatitis. A copy of the press release in which the top-line results were announced is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in the press release is summary information that is intended to be considered in the context of the more complete information included in the Company’s filings with the U.S. Securities and Exchange Commission (the “SEC”) and other public announcements that the Company has made and may make from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such update may be made through the filing of other reports or documents with the SEC.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 21, 2022
104	Cover Page Interactive Data File, formatted in inline XBRL

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 thereunto duly authorized.

TERNS PHARMACEUTICALS, INC.

Date: March 21, 2022

By: /s/ Bryan Yoon
Bryan Yoon
Chief Operating Officer and General Counsel



Terns Reports Top-line Results from Phase 1 AVIATION Trial of VAP-1 Inhibitor TERN-201

FOSTER CITY, Calif., March 21, 2022 (GLOBE NEWSWIRE) – Terns Pharmaceuticals, Inc. (“Terns” or the “Company”) (Nasdaq: TERN), a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates to address serious diseases such as non-alcoholic steatohepatitis (NASH) and obesity, today reported top-line results from Part 1 of the Company’s Phase 1b AVIATION Trial of TERN-201, a vascular adhesion protein-1 (VAP-1) inhibitor in development for the treatment of patients with NASH.

Part 1 of the AVIATION Trial met the primary safety endpoint. Compared to placebo, TERN-201 10 mg administered for 12 weeks to presumed NASH patients was generally well-tolerated with a similar incidence of adverse events (AEs) between the 10 mg treatment group and placebo. All AEs were mild to moderate. There were no treatment-emergent serious AEs (SAEs), including no cases of treatment-related monoamine oxidase inhibition (e.g., central nervous system toxicity), and no patients discontinued TERN-201 or the study due to any AE. While treatment with TERN-201 10 mg resulted in near complete (>98%) inhibition of plasma VAP-1 in most subjects, there were no meaningful changes in exploratory serum or imaging NASH biomarkers with TERN-201 10 mg relative to placebo, including corrected T1 (cT1), a measure of inflammation and fibrosis linked to clinical outcomes, as well as ALT, AST, GGT and CK-18.

Part 2 of the AVIATION Trial assessing 20 mg of TERN-201 remains ongoing, with top-line results expected in the second half of 2022. Terns will continue to analyze results from Part 1 of the AVIATION Trial to evaluate next steps for the TERN-201 program.

“We want to thank the patients, study teams and physicians who participated in the well-executed Part 1 of the AVIATION Trial,” said Erin Quirk, M.D., President, Chief Medical Officer and Head of R&D at Terns. “While the AVIATION results from Part 1 were disappointing, Terns is fortunate to have a broad pipeline, cash runway expected to fund operations into 2024 and a stellar team to support our pipeline activities. We look forward to the planned initiation of our Phase 2a trial of TERN-501 alone and in combination with TERN-101 for NASH in the first half of 2022 and our Phase 1 trial of TERN-601, an oral small-molecule GLP-1 receptor agonist for obesity, in 2023.”

About the AVIATION Trial

The AVIATION Trial (NCT04897594) is a multi-center, randomized, double-blind, dose-ranging, placebo-controlled, proof of concept, adaptive, Phase 1b clinical trial. The primary objective of the AVIATION trial is to evaluate the safety and tolerability of TERN-201 over 12 weeks of treatment in patients with presumed non-cirrhotic NASH. Secondary objectives included pharmacokinetics and assessment of pharmacodynamic effect on VAP-1 activity. The clinical trial is designed to be conducted in two parts (Part 1 and Part 2). Part 1 of the AVIATION Trial evaluated 10 mg TERN-201 over 12 weeks with a four-week follow-up period. The patients in Part 1 were randomized to receive placebo (n=10) or 10 mg TERN-201 (n=20), and patients in Part 2 are randomized to receive placebo or 20 mg TERN-201.

About TERN-201

TERN-201 is a highly selective, irreversible, covalent inhibitor of vascular adhesion protein-1 (VAP-1). VAP-1 is a transmembrane protein highly expressed in hepatic vascular endothelial cells that binds to proteins on the surface of white blood cells to facilitate their deceleration, binding and transmigration from the blood stream into the liver. VAP-1 has been shown to be over-expressed in the livers of patients with NASH and fibrosis. In Terns' Phase 1 first-in-human (SAD/MAD) clinical trial across 61 healthy subjects, TERN-201 was shown to be well-tolerated and fully suppress the enzymatic activity of VAP-1 at all evaluated doses with suppression persisting up to seven days after a single dose. In preclinical studies, TERN-201 showed significant dose-dependent reductions in liver inflammation and fibrosis in a model of liver injury. TERN-201 exhibits high selectivity for VAP-1, enhanced liver distribution and minimal potential for off-target inhibition of monoamine oxidases (MAOs). Terns received Fast Track Designation from the FDA for TERN-201 for the treatment of NASH in August 2020. TERN-201 was in-licensed from Eli Lilly and Company in March 2018 pursuant to an exclusive, worldwide license agreement.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates to address serious diseases such as NASH and obesity. Terns' pipeline includes three clinical stage development programs including an FXR agonist, a VAP-1 inhibitor and a THR- β agonist, and a preclinical small-molecule GLP-1 receptor agonist program. For more information, please visit: www.ternspharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about Terns Pharmaceuticals, Inc. (the “Company,” “we,” “us,” or “our”) within the meaning of the federal securities laws, including those related to the Company’s expectations of timing and potential results of the Company’s clinical trials and other development activities, including in relation to the ongoing Phase 1b AVIATION Trial of TERN-201; the therapeutic potential of TERN-201; the potential for vascular adhesion protein-1 (VAP-1) to be a therapeutic target for NASH; the potential utility and progress of the Company’s product candidates in NASH, including the clinical utility of the data from and the endpoints used in the AVIATION Trial; the Company’s clinical development plans and activities, including its plans for Part 2 of the AVIATION Trial and further development of TERN-201 in NASH; the Company’s expectations regarding the profile of its product candidates, including tolerability, safety, metabolic stability and pharmacokinetic profile; the Company’s anticipated cash runway; and the Company’s ability to continue to execute on its clinical strategy and plans. All statements other than statements of historical facts contained in this press release, including statements regarding the Company’s strategy, future financial condition, future operations, future trial results, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results and the implementation of the Company’s plans to vary materially, including the risks associated with the initiation, cost, timing, progress and results of the Company’s current and future research and development activities and preclinical studies and clinical trials. In particular, the impact of the COVID-19 pandemic on the Company’s ability to progress with its research, development, manufacturing and regulatory efforts, including the Company’s clinical trials for its product candidates, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. These risks are not exhaustive. For a detailed discussion of the risk factors that could affect the Company’s actual results, please refer to the risk factors identified in the Company’s SEC reports, including but not limited to its Annual Report on Form 10-K for the year ended December 31, 2021. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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