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): April 29, 2024

Terns Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39926**	**98-1448275**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1065 East Hillsdale Blvd. Suite 100 Foster City, California	**94404**
(Address of Principal Executive Offices)	**(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 7.01 Regulation FD Disclosure.

On April 29, 2024, Terns Pharmaceuticals, Inc. issued a press release announcing data from its ongoing Phase 1 pharmacokinetic study of TERN-701. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Terns Pharmaceuticals, Inc. on April 29, 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.

TERNS PHARMACEUTICALS, INC.

Date: April 29, 2024

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

Exhibit 99.1

Terns Pharmaceuticals Announces Data from Ongoing Phase 1 Pharmacokinetic Study of Allosteric BCR-ABL Inhibitor TERN-701 in Adult Healthy Volunteers and Highlights Potential for Competitive Differentiation

Ability to dose TERN-701 without regard to food represents a key potential differentiator within the allosteric BCR-ABL inhibitor class

Pharmacokinetic data show no clinically significant difference in exposure between fed and fasted dosing

Phase 1 CARDINAL trial evaluating TERN-701 in 2L+ CML patients remains ongoing, with interim data from initial cohorts anticipated in second half of 2024

FOSTER CITY, Calif., April 29, 2024 -- Terns Pharmaceuticals, Inc. ("Terns" or the "Company") (Nasdaq: TERN), a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology and obesity, today announced findings from a Phase 1 study of TERN-701 in Western healthy volunteers. The study is an ongoing Phase 1 open-label, single ascending dose trial to evaluate the pharmacokinetics (PK), food effect, safety and tolerability of TERN-701 in healthy adults. TERN-701 is Terns' proprietary, oral, potent, allosteric BCR-ABL inhibitor, a novel class of therapy for CML that has demonstrated superior efficacy and safety compared to traditional active-site tyrosine kinase inhibitors (TKIs).

"We are pleased with the interim findings from this healthy volunteer study, which indicate TERN-701 can be administered once-daily (QD) with or without food at doses that achieve clinically efficacious exposures. TERN-701 has the potential to be a differentiated BCR-ABL inhibitor with advantages over asciminib, including more convenient dosing to improve treatment options and quality of life for people living with CML," said Emil Kuriakose, MD, chief medical officer at Terns Pharmaceuticals.

"We are excited to see clinical PK data continuing to support once-daily dosing and new data showing lack of food effect with TERN-701. The ability to dose with or without food is a key potential differentiator from asciminib, the only currently approved allosteric BCR-ABL inhibitor, which requires three hours of fasting with each dose, and twice-daily dosing in multiple clinical settings. We look forward to reporting interim dose escalation data from the ongoing Phase 1 CARDINAL trial in the second half of 2024," concluded Dr. Kuriakose.

The Phase 1 single-ascending dose (SAD) trial is ongoing in the United States and has enrolled 32 healthy volunteers in four dose escalation cohorts of eight participants each to evaluate PK, food effect and safety and tolerability at single doses ranging from 20 mg to 160 mg. No clinically meaningful changes or trends were observed in clinical laboratory data, vital signs or electrocardiogram (ECG) parameters at any dose level. Across the dose range administered to date, TERN-701 PK was linear with a median half-life ranging from 8 to 12 hours. At the 80 mg and 160 mg doses, TERN-701 exposures over 24 hours met or exceeded the predicted efficacious concentrations based on preclinical data[1], consistent with observed clinical activity and safety at these doses in the ongoing Phase 1 study in China conducted by our partner, Hansoh Pharmaceuticals. Overall, the PK profile of TERN-701 in Western participants was generally consistent with that observed in the Phase 1 clinical study in Chinese CML patients.

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[1] Effective plasma IC90 for the native BCR-ABL KCL-22 cell line

Results of the food effect evaluation at 80 mg of TERN-701 showed no clinically significant differences in plasma exposures (area under curve, AUC) when dosed with a high-fat meal, relative to the fasted state. These results support potential dosing of TERN-701 with or without food, an initial differentiation for TERN-701 as a potentially best-in-class allosteric BCR-ABL inhibitor.

The Phase 1 healthy volunteer study remains ongoing and will proceed to enroll 320 mg and 400 mg dose cohorts. Terns plans to present these healthy volunteer data at an upcoming scientific conference.

Phase 1 CARDINAL Trial Design

The CARDINAL trial is a global, multicenter, open-label, two-part Phase 1 clinical trial to evaluate the safety, PK, and efficacy of TERN-701 in participants with previously treated CML. Part 1 is the dose escalation portion of the trial that will evaluate once-daily TERN-701 monotherapy in approximately 24-36 adults living with CML to be enrolled in up to five dose cohorts. Participants will have chronic phase CML with confirmed BCR-ABL and a history of treatment failure or suboptimal response to at least one second generation TKI (nilotinib, dasatinib or bosutinib). Participants who are intolerant to prior TKI treatment (including asciminib) are also allowed. The primary endpoints for Part 1 are the incidence of dose limiting toxicities (DLTs) during the first treatment cycle, and additional measures of safety and tolerability. Secondary endpoints include TERN-701 PK and efficacy assessments, such as hematologic and molecular responses as measured by the change from baseline in BCR-ABL transcript levels. The starting dose is 160 mg QD with dose escalations as high as 500 mg QD and the option to explore a lower dose of 80 mg QD.

Part 2 is the dose expansion portion of the trial that is planned to enroll approximately 40 patients, randomized to QD treatment with one of two doses of TERN-701 to be selected based on data from Part 1. The primary endpoint of the dose expansion portion of the trial is efficacy, measured by hematologic and molecular responses. Secondary endpoints include safety, tolerability and PK. The overall objective of the CARDINAL trial is to select the optimal dose(s) of TERN-701 to move forward to a potential pivotal trial in chronic phase CML.

The CARDINAL trial plans to enroll at sites in the U.S., Europe and other Terns global territories.

About TERN-701

TERN-701 is Terns' proprietary, oral, potent, allosteric BCR-ABL inhibitor specifically targeting the BCR-ABL myristoyl pocket and is in clinical development for chronic myeloid leukemia. Allosteric inhibitors, which bind to the myristoyl-binding pocket, represent a novel treatment class for CML and have the potential to address the shortcomings of active-site TKIs, including off-target activity and limited efficacy against active site resistance mutations. TERN-701 aims to address the limitations of active-site TKIs with the goal of achieving improved tumor suppression through a combination of potent activity against BCR-ABL including a broad range of mutations and improved safety and tolerability profiles. Hansoh's Phase 1 trial (NCT05367700) evaluating the tolerability, efficacy, and pharmacokinetics of once-daily TERN-701 (HS-10382) for CML in China is ongoing.

About Chronic Myeloid Leukemia

CML is a cancer that occurs when the blood-forming cells of the bone marrow overproduce white blood cells. In the United States, CML is an orphan indication with approximately 9,280 new cases expected to be diagnosed in 2024. Since the introduction of TKI therapy in 2001, CML has been transformed from a life-threatening disease to a life-long chronic condition for most patients. Despite improvements in outcomes with active-site targeting TKIs, many patients do not achieve long-term disease control with these therapies due to resistance or intolerance, leading patients to cycle through prior generation treatments. As a result, physicians and patients are seeking additional efficacious therapies for people whose tolerability, co-morbidity and/or drug-drug interaction profiles change over time, limiting their available treatment options, quality of life and the effectiveness of mainstay therapies. Allosteric BCR-ABL TKIs are the only class of drug to show efficacy and tolerability benefits compared with active-site TKIs, and represent an important advancement in the treatment of CML.

About Terns Pharmaceuticals
Terns Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology and obesity. Terns' pipeline includes three clinical stage development programs including an allosteric BCR-ABL inhibitor, a small-molecule GLP-1 receptor agonist, a THR-β agonist, and a preclinical GIPR modulator program. For more information, please visit: www.ternspharma.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements about the Company within the meaning of the federal securities laws, including those related to expectations, timing and potential results of the clinical trials and other development activities of the Company and its partners; the potential indications to be targeted by the Company with its small-molecule product candidates; the therapeutic potential of the Company's small-molecule product candidates; the potential for the mechanisms of action of the Company's product candidates to be therapeutic targets for their targeted indications; the potential utility and progress of the Company's product candidates in their targeted indications, including the clinical utility of the data from and the endpoints used in the Company's clinical trials; the Company's clinical development plans and activities, including the results of any interactions with regulatory authorities on its programs; the Company's expectations regarding the profile of its product candidates, including efficacy, tolerability, safety, metabolic stability and pharmacokinetic profile and potential differentiation as compared to other products or product candidates; the Company's plans for and ability to continue to execute on its current development strategy, including potential combinations involving multiple product candidates; the Company's plans and expectations around the addition of key personnel; and the Company's expectations with regard to its cash runway and sufficiency of its cash resources. 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, results and utility of the Company's current and future research and development activities and preclinical studies and clinical trials. 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, 2023. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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