# Terns Pharmaceuticals Reports Third Quarter 2023 Financial Results and Corporate Updates

November 14, 2023

*Announced global Phase 1 clinical trial design of TERN-701 (allosteric BCR-ABL) for CML with patient screening anticipated in December 2023 and interim top-line data expected in the second half of 2024*

*Dosed first participant in Phase 1 clinical trial of TERN-601 (oral GLP-1) for obesity with top-line data expected in the second half of 2024*

*Reported positive top-line data from Phase 2a DUET clinical trial that demonstrated TERN-501 (THR-β) has best-in-class potential based on overall profile of efficacy, tolerability and combinability*

*Cash, cash equivalents and marketable securities of $267 million expected to provide runway into 2026*

FOSTER CITY, Calif., Nov. 14, 2023 (GLOBE NEWSWIRE) -- 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, obesity and non-alcoholic steatohepatitis (NASH), today reported financial results for the quarter ended September 30, 2023 and provided corporate updates.

“Throughout the third quarter and in recent weeks, we made meaningful progress across all three of our clinical development programs, opening U.S. Investigational New Drug (IND) applications, both for our allosteric BCR-ABL inhibitor TERN-701 for chronic myeloid leukemia (CML) and our lead small molecule oral GLP-1 agonist TERN-601 for obesity, and releasing Phase 2 data for our thyroid hormone receptor β agonist TERN-501 from the DUET study in NASH patients. We are now preparing for a data-rich 2024, with expected proof of concept readouts from our clinical trials in CML and obesity,” stated Erin Quirk, MD, president and head of research and development at Terns. “The advances we are making, which are supported by strong clinical and scientific data, give us even greater confidence in our approach to bring better chemistry to the development of small-molecule candidates with clinically validated mechanisms to address oncologic and metabolic diseases with large unmet medical needs.”

“We are excited to have dosed the first participant in our first-in-human trial of TERN-601 to treat obesity as preclinical data suggest it has potential for broad metabolic benefits in obesity, oral once-daily dosing, and suitability for combination therapy. We are also looking forward to dosing the first participants in our Phase 1 trial of TERN-701 as a treatment for CML while leveraging insights from our partner’s ongoing Phase 1 trial in China to support a starting dose that appears safe and clinically active based on emerging early clinical data,” added Dr. Quirk.

**Recent Pipeline Developments and Anticipated Milestones**

TERN-701: Oral, allosteric BCR-ABL tyrosine kinase inhibitor (TKI) for CML

- In October, Terns announced the Investigational New Drug (IND) clearance from the U.S. FDA and design of the CARDINAL Phase 1 clinical trial of TERN-701 for the treatment of CML
  - CARDINAL is a global, multicenter, open-label, two-part Phase 1 clinical trial to evaluate the safety, pharmacokinetics (PK), and efficacy of TERN-701 in participants with previously treated CML
  - The dose escalation portion (Part 1) of the trial will evaluate once-daily TERN-701 monotherapy in approximately 24-36 adults living with CML to be enrolled in up to five dose cohorts; screening for Part 1 is anticipated to begin in December 2023
    - Primary endpoints of the CARDINAL dose escalation portion include incidence of dose limiting toxicities (DLTs) during the first treatment cycle and additional measures of safety and tolerability
    - Secondary endpoints include 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 (once-daily), with the option to explore a lower dose of 80 mg QD
  - The dose expansion portion (Part 2) of the CARDINAL trial will initiate after dose escalation data are available and will enroll approximately 40 patients, randomized to once-daily treatment with one of two doses of TERN-701 to be selected based on data from Part 1
    - The primary endpoint of the CARDINAL dose expansion portion is efficacy, measured by hematologic and molecular responses. Secondary endpoints include safety, tolerability and PK
- The CARDINAL trial plans to enroll at sites in the United States, Europe and other global territories
- Global site identification and trial start-up activities are ongoing, with interim top-line readouts from initial cohorts expected in the second half of 2024

TERN-601: Oral, small-molecule glucagon-like peptide-1 (GLP-1) receptor agonist for obesity

- Earlier this month, Terns announced that the first participant was dosed in the Phase 1 first-in-human clinical trial of TERN-601 for obesity

- The Phase 1 trial is a randomized, double-blind, placebo-controlled single and multiple-ascending dose (SAD and MAD) trial to assess the safety, tolerability, PK and pharmacodynamics (PD) of TERN-601 in healthy adults with obesity or who are overweight
    - Part 1 (SAD) is a SAD study that will evaluate up to six once-daily TERN-601 dose levels in approximately 40 healthy participants
        - The starting TERN-601 dose is 30 mg, with subsequent dose levels based on review of emerging safety and PK data from prior cohorts
    - Part 2 (MAD) of the trial will enroll approximately 72 obese and overweight healthy participants and will include cohorts incorporating titration of TERN-601 administered for 28-days at doses to be selected based on data from Part 1

- Top-line, 28-day proof of concept weight loss data from the Phase 1 trial is expected in the second half of 2024

TERN-501: Oral, thyroid hormone receptor-β (THR-β) agonist for NASH

- Phase 2a DUET trial data evaluating TERN-501 for the treatment of NASH was featured in an oral late-breaking presentation at The Liver Meeting 2023:
    - The oral presentation titled, “Topline results from a 12-week Phase 2a Trial (DUET) evaluating TERN-501, a highly selective thyroid hormone receptor (THR) β agonist, either as monotherapy or in combination with TERN-101, a nonsteroidal farnesoid X receptor (FXR) agonist, demonstrated significant reductions in MR-based liver fat content and fibroinflammation in patients with presumed NASH,” was delivered by Mazen Noureddin, MD, MHSc, Professor of Medicine, Academic Institute at Houston Methodist, Director of Houston Research Institute

- Terns reported positive top-line data from the Phase 2a DUET trial of TERN-501 for the treatment of NASH in August
    - TERN-501 met all primary and secondary endpoints
    - TERN-501 demonstrated dose dependent MRI-PDFF reductions at Week 12 as a once-daily, low dose, and combinable oral therapy
    - TERN-501 (6 mg) showed statistically significant mean relative liver fat content reduction of 45% as assessed by MRI-PDFF with 64% of patients achieving >30% PDFF reduction
    - All TERN-501 doses were well-tolerated with no gastrointestinal and no cardiovascular safety signals

**Corporate Updates**

- In August 2023, Terns announced the departure of Senthil Sundaram, the Company’s former chief executive officer, for health reasons. Terns is conducting an ongoing search for a permanent chief executive officer. In the interim, Dr. Quirk continues to assume day-to-day leadership of the Company and serve as principal executive officer. In addition, the Board has engaged board director, Jill M. Quigley, JD as senior advisor and strategy officer on an interim basis until a permanent chief executive officer is appointed.

**Third Quarter 2023 Financial Results**

**Cash Position:** As of September 30, 2023, cash, cash equivalents and marketable securities were $266.6 million, as compared with $283.1 million as of December 31, 2022. Based on its current operating plan, Terns expects these funds will be sufficient to support its planned operating expenses into 2026.

**Research and Development (R&D) Expenses:** R&D expenses were $14.8 million for the quarter ended September 30, 2023, as compared with $12.2 million for the quarter ended September 30, 2022.

**General and Administrative (G&A) Expenses:** G&A expenses were $18.4 million for the quarter ended September 30, 2023, as compared with $5.1 million for the quarter ended September 30, 2022.

**Net Loss:** Net loss was $29.8 million for the quarter ended September 30, 2023, as compared with $16.8 million for the quarter ended September 30, 2022.

**Terns Pharmaceuticals, Inc.**

**Condensed Consolidated Statements of Operations**
**(Unaudited; in thousands except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |

| | | | | |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 14,831 | $ 12,161 | $ 46,038 | $ 28,959 |
| General and administrative | 18,353 | 5,131 | 32,462 | 16,242 |
| Total operating expenses | 33,184 | 17,292 | 78,500 | 45,201 |
| Loss from operations | (33,184) | (17,292) | (78,500) | (45,201) |
| Interest income | 3,480 | 499 | 9,568 | 782 |
| Other expense, net | (5) | (14) | (69) | (64) |
| Loss before income taxes | (29,709) | (16,807) | (69,001) | (44,483) |
| Income tax expense | (58) | (13) | (190) | (40) |
| Net loss | $ (29,767) | $ (16,820) | $ (69,191) | $ (44,523) |
| Net loss per share, basic and diluted | $ (0.42) | $ (0.44) | $ (0.98) | $ (1.50) |
| Weighted average common stock outstanding, basic and diluted | 71,530,180 | 38,511,655 | 70,897,320 | 29,743,579 |

**Terns Pharmaceuticals, Inc.**
**Selected Balance Sheet Data**
**(Unaudited; in thousands)**

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 266,600 | $ 283,114 |
| Total assets | 271,687 | 287,026 |
| Total liabilities | 13,262 | 10,083 |
| Total stockholders' equity | 258,425 | 276,943 |

**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, obesity and NASH. 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 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 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, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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