Tempest Reports Year End 2024 Financial Results and Provides Business Update

March 27, 2025

• Granted Both Orphan Drug & Fast Track designations for Amezalpat (TPST-1120) for the treatment of patients with Hepatocellular Carcinoma (HCC)

• Announced Agreement with Roche to Support Advancement of Amezalpat Combination Therapy into First-Line HCC Pivotal Trial

• Received FDA "Study May Proceed" letter for Phase 2 trial of TPST-1495 for the treatment of Familial Adenomatous Polyposis (FAP)

BRISBANE, Calif., March 27, 2025 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-class[1] targeted and immune-mediated therapeutics to fight cancer, today reported financial results for the year ended 2024 and provided a corporate update.

"2024 was another year filled with significant progress and milestone achievements that position Tempest for a successful future," said Stephen Brady, president and chief executive officer of Tempest. "Despite challenging capital markets, our lean team excelled, reporting key OS data from the ongoing randomized Phase 2 trial of amezalpat in first-line hepatocellular carcinoma. As previously announced, we have secured broad regulatory agreement with both the FDA and EMA on the Phase 3 plan and received both Orphan Drug and Fast Track designations from the FDA. We also advanced our second clinical program, TPST-1495, with a Phase 2 clinical trial for the treatment of patients with FAP, with data expected in 2026. Our focus remains on execution with excellence while securing the resources necessary to drive these promising drug candidates forward."

2024 & Recent Accomplishments

Amezalpat (TPST-1120) (clinical PPARα antagonist)**:**

- Granted both Orphan Drug and Fast Track designations by the U.S. Food and Drug Administration (FDA) for amezalpat for the treatment of patients with HCC.
- Received a "Study May Proceed" letter from the FDA to evaluate amezalpat in combination with atezolizumab (TECENTRIQ®) and bevacizumab (Avastin®), the current standard of care for unresectable or metastatic HCC, in a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic HCC.
- Announced an agreement with F. Hoffmann-La Roche Ltd. (Roche) to advance the evaluation of amezalpat in combination with atezolizumab and bevacizumab into a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic HCC.
- Announced positive feedback from the end-of-Phase 2 meeting with the FDA for amezalpat in combination with atezolizumab and bevacizumab to treat first-line unresectable or metastatic HCC.
- Reported new positive survival data from the ongoing global randomized Phase 1b/2 clinical study demonstrating that amezalpat delivered a six-month improvement in median overall survival (OS) when combined with atezolizumab and bevacizumab in comparison to atezolizumab and bevacizumab alone, the standard of care, in the first-line treatment of patients with unresectable or metastatic HCC.
- Published positive data from Phase 1 trial of amezalpat in patients with advanced solid tumors in the Journal of Cancer Research Communications. Data showed that amezalpat demonstrated clinical activity, including tumor shrinkage, even in PD-1 inhibitor-refractory and immune-compromised cancers. These data complement the positive Phase 1b/2 data reported in October 2023 and June 2024 from a global randomized study of amezalpat in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC.
- Reported new preclinical data at the 2024 American Association for Cancer Research (AACR) Annual Meeting demonstrating that amezalpat reduces kidney cancer growth as a monotherapy, while also showing increased inhibition when combined with frontline chemotherapy and immunotherapy. These data further support the clinical benefit observed in the amezalpat Phase 1 data presented in an oral presentation at ASCO 2022.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist)
  - Received a "Study May Proceed" letter from the FDA to evaluate TPST-1495 in a Phase 2 Trial for the treatment of FAP.
- **Corporate:**
  - Expanded leadership team to strengthen global clinical expertise with the appointments of Troy M. Wagner as Vice

President of Quality Assurance and Sheldon Mullins as Vice President of Regulatory Affairs.

Potential Future Milestones

- **Amezalpat (TPST-1120)** (clinical PPARα antagonist)
  - Plan to advance amezalpat into a registrational study in first-line liver cancer patients, subject to obtaining additional resources.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist)
  - Plan to advance TPST-1495 into a Phase 2 study in patients with FAP under the auspices of the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute (NCI) Division of Cancer Prevention in 2025, with data expected in 2026.

Financial Results

Year End 2024

- Tempest ended the year with $30.3 million in cash and cash equivalents, compared to $39.2 million on December 31, 2023. The decrease was primarily due to cash used in operating activities, offset by proceeds from the issuance of common stock of $28.6 million from the at-the-market offering program.
- Net loss and net loss per share for the year were $41.8 million and $1.50, respectively, compared to $29.5 million and $1.91, respectively, for the same period in 2023.
- Research and development expenses for the year were $28.5 million compared to $17.5 million for the same period in 2023. The $11.0 million increase was primarily due to an increase in costs incurred from engaging contract research and manufacturing organizations in preparation for our pivotal Phase 3 trial of amezalpat for the treatment of first-line HCC.
- General and administrative expenses for the year were $13.6 million compared to $11.7 million for the same period in 2023. The $1.9 million increase was primarily due to an increase in stock-based compensation expense due to increased headcount as well as an increase in expenses related to legal and consulting services.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company advancing a diverse portfolio of small molecule product candidates containing tumor-targeted and/or immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's novel programs range from early research to later-stage investigation in a randomized global study in first-line cancer patients. Tempest is headquartered in Brisbane, California. More information about Tempest can be found on the company's website at www.tempesttx.com.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Securities Act")) concerning Tempest Therapeutics, Inc. These statements may discuss goals, intentions, and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Tempest Therapeutics, as well as assumptions made by, and information currently available to, management of Tempest Therapeutics. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "could", "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions. All statements that are not historical facts are forward-looking statements, including any statements regarding: the design, initiation, progress, timing, scope and results of clinical trials, including the anticipated Phase 3 study for amezalpat and Phase 2 Trial of TPST-1495; anticipated therapeutic benefit and regulatory development of the Company's product candidates; the Company's ability to advance into a late-stage clinical company; the Company's ability to secure resources and funding; and the Company's ability to achieve its operational plans. Forward-looking statements are based on information available to Tempest Therapeutics as of the date hereof and are not guarantees of future performance. Any factors may cause differences between current expectations and actual results, including: unexpected safety or efficacy data observed during preclinical or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied are discussed in greater detail in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and other documents filed by the Company from time to time with the Securities and Exchange Commission. Except as required by applicable law, Tempest Therapeutics undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Tempest Therapeutics' views as of any date subsequent to the date of this press release and should not be relied upon as prediction of future events. In light of the foregoing, investors are urged not to rely on any forward-looking statement in reaching any conclusion or making any investment decision about any securities of Tempest Therapeutics.

TEMPEST THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands)

	December 31, 2024	December 31, 2023

Assets		
Current assets		
Cash and cash equivalents	$ 30,268	$ 39,230
Prepaid expenses and other current assets	1,206	1,133
Total current assets	31,474	40,363
Property and equipment, net	886	840
Operating lease right-of-use assets	8,643	9,952
Other noncurrent assets	485	448
Total assets	$ 41,488	$ 51,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,450	$ 845
Accrued expenses and other	2,726	1,673
Current loan payable, net	6,354	4,285
Current operating lease liabilities	869	952
Accrued compensation	1,762	1,543
Interest payable	59	113
Total current liabilities	14,220	9,411
Loan payable, net	-	6,264
Operating lease liabilities	8,142	9,160
Total liabilities	22,362	24,835
Stockholders' equity		
Common stock	44	22
Additional paid-in capital	226,188	192,009
Accumulated deficit	(207,106)	(165,263)
Total stockholders' equity	19,126	26,768
Total liabilities and stockholders' equity	$ 41,488	$ 51,603

TEMPEST THERAPEUTICS, INC.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Year ended December 31, 2024	Year ended December 31, 2023
Expenses:		
Research and development	$ 28,476	$ 17,498
General and administrative	13,550	11,659
Operating loss	(42,026)	(29,157)
Other income (expense), net:		
Interest expense	(1,316)	(1,449)
Interest and other income, net	1,499	1,115
Net loss	$ (41,843)	$ (29,491)
Net loss per share	$ (1.50)	$ (1.91)

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[1] If approved by the U.S. Food and Drug Administration (FDA).