Tempest Reports Third Quarter 2024 Financial Results and Provides Business Update

November 12, 2024

- *Building upon a successful end-of-Phase 2 meeting, received FDA "Study May Proceed" letter for pivotal Phase 3 trial of amezalpat (TPST-1120) combination therapy to treat first-line HCC*
- *Announced agreement with Roche to support advancement of amezalpat into first-line HCC pivotal Phase 3 trial*
- *Received final funding approval from NCI to move TPST-1495 into a Phase 2 trial in FAP*
- *Expanded leadership team to strengthen global clinical expertise*

BRISBANE, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-class[i] targeted and immune-mediated therapeutics to fight cancer, today reported financial results for the quarter ended September 30, 2024, and provided a corporate update.

"During the third quarter, the team continued to move amezalpat successfully towards the pivotal study, achieving important milestones on both the regulatory and business fronts," said Stephen Brady, president and chief executive officer of Tempest. "Based on the positive randomized Phase 2 data and a Phase 3 plan we believe is designed for success, we were thrilled to receive broad agreement with the FDA. Coupled with Roche's support for the Phase 3 study, the third quarter further solidified the foundation of a pivotal study that we hope will result in a new and meaningful therapy for first-line HCC patients."

Recent Highlights

- **Amezalpat (TPST-1120)** (clinical PPARα antagonist):
  - Received a "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) to evaluate amezalpat in combination with atezolizumab (Tecentriq®) and bevacizumab (Avastin®), the current standard of care for unresectable or metastatic hepatocellular carcinoma (HCC), in a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic hepatocellular carcinoma.
  - 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, a form of liver cancer with high unmet need.
    - Under the agreement, Roche will supply atezolizumab globally and Tempest will sponsor and lead the pivotal study. The agreement builds on a clinical collaboration between the companies pursuant to which amezalpat was combined with atezolizumab and bevacizumab in first-line HCC patients and compared to atezolizumab and bevacizumab alone in a randomized Phase 1b/2 study. Tempest retains all development and commercial rights to amezalpat.
  - 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. Key outcomes included:
    - Agreement on Phase 3 study design, including the standard-of-care control arm and the primary and secondary study endpoints.
    - Agreement on appropriateness of the current amezalpat dose and schedule for the Phase 3 study.
    - Agreement on the Phase 3 statistical plan, including a pre-specified early efficacy analysis that the company currently estimates could shorten the time to primary analysis by up to 8 months.
- **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.

Other Potential Future Milestones

- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist)
  - Plan to advance TPST-1495 into a Phase 2 study in patients with Familial Adenomatous Polyposis (FAP) in 2024 or early 2025 under the auspices of the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute (NCI) Division of Cancer Prevention.
  - Expect to disclose data from the TPST-1495 Phase 1 combination arm in patients with advanced endometrial cancer in 2025.

Financial Results

Third Quarter 2024

- Tempest ended the quarter with $22.1 million in cash and cash equivalents, compared to $39.2 million on December 31, 2023. Subsequent to September 30, 2024, Tempest raised an additional $19.9 million in net proceeds through the sale of 17 million shares of common stock under the Company's at-the-market (ATM) program.
- Net loss and net loss per share for the quarter ended September 30, 2024, were $10.6 million and $0.41, respectively, compared to $6.8 million and $0.48, respectively, for the same period in 2023.
- Research and development expenses for the quarter were $7.6 million compared to $4.2 million for the same period in 2023. The $3.4 million increase was primarily due to an increase in costs incurred from contract research and manufacturing organizations.
- General and administrative expenses for the quarter were $3.0 million compared to $2.4 million for the same period in 2023. The $0.6 million increase was primarily due to an increase in stock-based compensation, and consulting and professional services.

Year-to-Date

- Cash used in operating activities for the nine months ended September 30, 2024 was $22.9 million.
- Net loss and net loss per share for the nine months ended September 30, 2024 were $28.0 million and $1.19, respectively, compared to $22.0 million and $1.57, respectively, for the same period in 2023.
- Research and development expenses for the nine months ended September 30, 2024 were $17.7 million compared to $13.3 million for the same period in 2023. The $4.4 million increase was primarily due to an increase in costs incurred from contract research and manufacturing organizations, as well as an increase in stock-based compensation.
- General and administrative expenses for the nine months ended September 30, 2024 were $10.4 million compared to $8.3 million for the same period in 2023. The $2.1 million increase was primarily due to an increase in stock-based compensation as well as 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; Roche's future supply of atezolizumab for use in the Company's pivotal Phase 3 trial; anticipated therapeutic benefit and regulatory development of the Company's product candidates; the Company's anticipated cash runway; the Company's ability to deliver on potential value-creating milestones; the Company's ability to advance into a late-stage clinical company; 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 22,116	$ 39,230
Prepaid expenses and other current assets	1,436	1,133

Total current assets	23,552	40,363
Property and equipment, net	932	840
Operating lease right-of-use assets	8,904	9,952
Other noncurrent assets	448	448
Total assets	$ 33,836	$ 51,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,697	$ 845
Accrued expenses	1,459	1,673
Current loan payable, net	8,504	4,285
Current operating lease liabilities	828	952
Accrued compensation	1,402	1,543
Interest payable	83	113
Total current liabilities	13,973	9,411
Loan payable, net	-	6,264
Operating lease liabilities	8,406	9,160
Total liabilities	22,379	24,835
Stockholders' equity		
Common stock	27	22
Additional paid-in capital	204,723	192,009
Accumulated deficit	(193,293)	(165,263)
Total stockholders' equity	11,457	26,768
Total liabilities and stockholders' equity	$ 33,836	$ 51,603

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

	Three months ended September 30, 2024	Three months ended September 30, 2023	Nine months ended September 30, 2024	Nine months ended September 30, 2023
Expenses:				
Research and development	$ 7,557	$ 4,221	$ 17,734	$ 13,315
General and administrative	2,994	2,371	10,374	8,328
Operating loss	(10,551)	(6,592)	(28,108)	(21,643)
Other income (expense), net:				
Interest expense	(329)	(373)	(1,069)	(1,072)
Interest and other income, net	324	179	1,147	712
Net loss	$ (10,556)	$ (6,786)	$ (28,030)	$ (22,003)
Net loss per share	$ (0.41)	$ (0.48)	$ (1.19)	$ (1.57)

Investor Contacts:

Sylvia Wheeler
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com

Aljanae Reynolds
Wheelhouse Life Science Advisors

areynolds@wheelhouselsa.com

[i] If approved by the FDA