Tempest Reports Second Quarter 2024 Financial Results and Provides Business Update

August 8, 2024

- *Unveiled new positive survival data for amezalpat (TPST-1120) in randomized first-line hepatocellular carcinoma ("HCC") study demonstrating:*
  - *Survival benefit maintained across key subpopulations*
  - *a six-month improvement over control arm in median survival*
  - *a strong 0.65 hazard ratio, maintained since 0.59 observed 10 months earlier*
- *Advancing amezalpat towards a pivotal Phase 3 trial in first-line HCC*
- *Planning to move TPST-1495 into a Phase 2 in FAP*

BRISBANE, Calif., Aug. 08, 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 June 30, 2024, and provided a corporate update.

"During the second quarter, amezalpat demonstrated positive survival benefit as a potential treatment for first-line liver cancer patients," said Stephen Brady, president and chief executive officer of Tempest. "Improving survival for these patients with the right safety profile is our goal and is also the primary global regulatory endpoint for this indication. This remarkable six-month improvement in survival compared to the standard of care, and maintenance of a strong hazard ratio, gives us confidence in the potential success of the program. These data point to the potential of amezalpat to help HCC patients in a meaningful way, and we're excited to be moving the program towards a pivotal study."

Recent Highlights

- **Amezalpat (TPST-1120)** (clinical PPARα antagonist):
  - Reported new positive survival data from the ongoing global randomized Phase 1b/2 clinical study demonstrating amezalpat (TPST-1120) delivered a six-month improvement in median overall survival ("OS") when combined with atezolizumab and bevacizumab in comparison to atezolizumab and bevacizumab alone in the first-line treatment of patients with unresectable or metastatic HCC. At the cutoff date of February 14, 2024, the new data from 40 patients randomized to the amezalpat arm and 30 patients randomized to the control arm showed:
    - 21-month median OS for the amezalpat arm versus 15 month for the control arm, a six-month survival advantage
      - 20/40 patients remain in survival follow up in the amezalpat arm, compared to 9/30 patients in the control arm
      - The survival benefit was maintained across key subpopulations
    - 0.65 hazard ratio ("HR") for OS, revealing a stable HR since the top-line analysis 10 months earlier when the HR was 0.59
    - Manageable safety profile consistent with Phase 1 data
  - 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 TPST-1120 Phase 1 data presented in an oral presentation at ASCO 2022.
  - 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, and was well tolerated both as monotherapy and in combination with nivolumab. These data complement the positive Phase 1b/2 data reported in October 2023 from a global randomized study of amezalpat in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC.

Potential Future Milestones

- **Amezalpat (TPST-1120)** (clinical PPARα antagonist)
  - Plan to advance amezalpat into a registrational Phase 3 study in first-line HCC patients, subject to obtaining feedback from the FDA.
- **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 under the auspices of the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute

("NCI") Division of Cancer Prevention, subject to final approval of NCI.
  - Expect to report data from the combination arm at the two highest TPST-1495 doses in patients with advanced endometrial cancer, where prostaglandin signaling is implicated, in 2024.

Financial Results

Second Quarter 2024

- Tempest ended the quarter with $31.1 million in cash and cash equivalents, compared to $39.2 million on December 31, 2023.
- Net loss and net loss per share for the quarter ended June 30, 2024, were $9.6 million and $0.42, respectively, compared to $7.6 million and $0.54, respectively, for the same period in 2023.
- Research and development expenses for the quarter were $5.8 million compared to $4.4 million for the same period in 2023. The $1.4 million increase was primarily due to an increase in costs incurred from contract research and manufacturing organizations, as well as stock-based compensation.
- General and administrative expenses for the quarter were $3.7 million compared to $3.1 million for the same period in 2023. The $0.6 million increase was primarily due to an increase in stock-based compensation expense as well as legal and consulting services.

Year-to-Date

- Cash used in operating activities for the six months ended June 30, 2024 was $12.7 million.
- Net loss and net loss per share for the six months ended June 30, 2024 were $17.5 million and $0.78, respectively, compared to $15.2 million and $1.09, respectively, for the same period in 2023.
- Research and development expenses for the six months ended June 30, 2024 were $10.2 million compared to $9.1 million for the same period in 2023. The $1.1 million increase was primarily due to an increase in costs incurred from contract research and manufacturing organizations, as well as stock-based compensation.
- General and administrative expenses for the six months ended June 30, 2024 were $7.4 million compared to $6.0 million for the same period in 2023. The $1.4 million increase was primarily due to an increase in stock-based compensation expense 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; 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 June 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)

	June 30, 2024	December 31, 2023

Assets		
Current assets		
Cash and cash equivalents	$ 31,124	$ 39,230
Prepaid expenses and other current assets	424	1,133
Total current assets	31,548	40,363
Property and equipment, net	1,014	840
Operating lease right-of-use assets	9,159	9,952
Other noncurrent assets	448	448
Total assets	$ 42,169	$ 51,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,357	$ 845
Accrued expenses	2,379	1,673
Current loan payable, net	8,645	4,285
Current operating lease liabilities	939	952
Accrued compensation	1,133	1,543
Interest payable	106	113
Total current liabilities	14,559	9,411
Loan payable, net	2,008	6,264
Operating lease liabilities	8,663	9,160
Total liabilities	25,230	24,835
Stockholders' equity		
Common stock	24	22
Additional paid-in capital	199,652	192,009
Accumulated deficit	(182,737)	(165,263)
Total stockholders' equity	16,939	26,768
Total liabilities and stockholders' equity	$ 42,169	$ 51,603

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

	Three months ended June 30, 2024	Three months ended June 30, 2023	Six months ended June 30, 2024	Six months ended June 30, 2023
Expenses:				
Research and development	$ 5,837	$ 4,416	$ 10,177	$ 9,094
General and administrative	3,745	3,054	7,379	5,957
Operating loss	(9,582)	(7,470)	(17,556)	(15,051)
Other income (expense), net:				
Interest expense	(372)	(355)	(740)	(699)
Interest and other income, net	384	244	822	533
Net loss	$ (9,570)	$ (7,581)	$ (17,474)	$ (15,217)
Net loss per share	$ (0.42)	$ (0.54)	$ (0.78)	$ (1.09)

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