Tempest Reports Year End 2023 Financial Results and Provides Business Update

March 19, 2024

- *Announced positive randomized first-line HCC data showing superiority of TPST-1120 combination therapy across multiple study endpoints compared to standard of care*
- *Reported new biomarker data in two important subpopulations, PD-L1 negative and b-catenin mutant patients, consistent with MoA of TPST-1120*
- *Preparing to move TPST-1120 into a pivotal Phase 3 trial in HCC and TPST-1495 into a Phase 2 in FAP*

BRISBANE, Calif., March 19, 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 year ended 2023 and provided a corporate update.

"2023 was a transformative year for Tempest. We announced strong positive randomized data showing the benefit of TPST-1120 combination therapy compared to standard-of-care in first-line liver cancer," said Stephen Brady, president and chief executive officer of Tempest. "These data also showed the predicted positive effect of TPST-1120 in two subpopulations that are common in liver cancer, i.e., patients with PD-L1 negative and cold tumors, as well as patients with a b-catenin mutation, and we believe set up the program for a pivotal Phase 3 trial. We look forward to 2024 as the year Tempest evolves towards becoming a late-stage clinical organization."

2023 Accomplishments

- **TPST-1120** (clinical PPARα antagonist):
  - Reported positive interim data in April 2023 from the ongoing randomized Phase 1b/2 clinical study evaluating TPST-1120 in combination with the standard-of-care regimen of atezolizumab and bevacizumab in previously untreated patients with advanced unresectable or metastatic hepatocellular carcinoma ("HCC"), compared to patients treated with the standard of care regimen alone. The data demonstrated clinically meaningful improvement in multiple categories and signaled the potential superiority of the TPST-1120 arm in the primary analysis planned for later in the year.
  - Reported updated positive data from the ongoing randomized study in October 2023 demonstrating clinical superiority of TPST-1120, when combined with atezolizumab and bevacizumab, as compared to the standard-of-care regimen, across multiple study endpoints in first-line HCC. Data from 40 patients randomized to the TPST-1120 arm and 30 patients randomized to the control arm, with a median follow-up of 9.2 and 9.9 months, respectively, showed:
    - Confirmed objective response rate ("cORR" or "confirmed ORR") of 30% for the TPST-1120 triplet arm (an increase from 17% in the earlier interim analysis), as compared to 13.3% for the atezolizumab + bevacizumab control arm; duration of response ("DoR") not yet reached.
    - Hazard ratio favors the TPST-1120 arm for key survival endpoints
      - Progression free survival ("PFS"): median PFS of 7 mo (5.6 mo, 13.8 mo) for TPST-1120 arm versus 4.27 mo (2.8 mo, 7.3 mo) for the control arm; HR of 0.7 favors TPST-1120 arm and is not yet mature
      - Overall survival ("OS"): median OS not reached for the TPST-1120 arm (10.84 mo, NE) versus 15.1 mo (7.49 mo, NE) for the control arm; HR 0.59 favors TPST-1120 arm and is not yet mature
    - 40% of the patients in the TPST-1120 arm were on treatment (16/40) compared to 16.7% in the atezolizumab + bevacizumab control arm (5/30)
    - 72.5% of the patients on the TPST-1120 arm were on study (29/40), compared to 46.7% on the atezolizumab + bevacizumab control arm (14/30)
    - TPST-1120 remains well tolerated, with safety data comparable between the two arms
- Presented new translational biomarker findings at the 2023 American Association for Cancer Research (AACR) Annual Meeting from the completed monotherapy and nivolumab combination therapy dose escalation Phase 1 trial in patients with advanced solid tumors, which showed on-target changes in gene signatures in the peripheral blood that were dependent upon drug exposure levels. In addition, distinct on-target changes in both lipid profile and NF-κB pathway regulated immune response gene signatures were observed in patients who achieved a RECIST response, compared with non-responders, following treatment with TPST-1120 and nivolumab.
- Presented data at the Society for Immunotherapy of Cancer (SITC) 2023 Spring Scientific Meeting highlighting biomarker data from the Phase 1 trial showing an association between observed clinical benefit of TPST-1120 and fatty acid oxidation

perturbations and gene expression.

- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist)
  - Presented Phase 1 clinical trial data at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting showing that in a diverse and treatment-refractory patient population, treatment with TPST-1495 as a monotherapy and in combination with pembrolizumab resulted in tumor shrinkage and prolonged stable disease in certain patients, as well as a durable confirmed partial response in a combination therapy patient with microsatellite stable colorectal cancer, an indication not normally responsive to immunotherapy.
  - Announced publication in Cancer Research Communications of data highlighting the increased potency of TPST-1495 against prostaglandin-driven tumor models by blocking EP2 and EP4 together.
  - Continued enrollment of an endometrial cancer-specific arm investigating the two highest doses of TPST-1495 in combination with pembrolizumab.

Potential Future Milestones

- **TPST-1120** (clinical PPARα antagonist)
  - Expect to announce updated data from the ongoing randomized study in first-line liver cancer patients in 2024.
  - Plan to advance TPST-1120 into a registrational study in first-line liver cancer 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") under the auspices of the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute ("NCI") Division of Cancer Prevention in 2024, 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 in 2024.

Financial Results

Year End 2023

- Tempest ended the year with $39.2 million in cash and cash equivalents, compared to $31.2 million on December 31, 2022. The increase was primarily due to proceeds from the issuance of common stock of $35.6 million from the at-the-market offering program, offset by cash used in operating activities.
- Net loss and net loss per share for the year were $29.5 million and $1.91, respectively, compared to $35.7 million and $3.09, respectively, for the same period in 2022.
- Research and development expenses for the year were $17.5 million compared to $22.5 million for the same period in 2022. The $5.0 million decrease was primarily due to a decrease in costs incurred from contract research organizations and third-party vendors.
- General and administrative expenses for the year were $11.7 million compared to $12.1 million for the same period in 2022. The $0.4 million decrease was primarily due to a decrease in consulting and professional services.
- Based on current cash and operating plan, Tempest expected to have sufficient resources to fund operations into the second quarter of 2025.

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 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, 2023 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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 39,230	$ 31,230
Insurance recovery of legal settlement	-	450
Prepaid expenses and other current assets	1,133	1,270
Total current assets	40,363	32,950
Property and equipment, net	840	1,060
Operating lease right-of-use assets	9,952	11,650
Other noncurrent assets	448	429
Total assets	$ 51,603	$ 46,089
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 845	$ 1,108
Accrued legal settlement	-	450
Accrued expenses and other	1,673	2,961
Current loan payable, net	4,285	-
Current operating lease liabilities	952	1,413
Accrued compensation	1,543	1,248
Interest payable	113	97
Total current liabilities	9,411	7,277
Loan payable, net	6,264	10,371
Operating lease liabilities	9,160	10,330
Total liabilities	24,835	27,978
Stockholders' equity		
Common stock	22	11
Additional paid-in capital	192,009	153,872
Accumulated deficit	(165,263)	(135,772)
Total stockholders' equity	26,768	18,111
Total liabilities and stockholders' equity	$ 51,603	$ 46,089

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

	Year ended December 31, 2023	Year ended December 31, 2022
Expenses:		
Research and development	$ 17,498	$ 22,527

General and administrative	11,659	12,113
Operating loss	(29,157)	(34,640)
Other income (expense), net:		
Interest expense	(1,449)	(1,618)
Interest and other income, net	1,115	549
Net loss	$ (29,491)	$ (35,709)
Net loss per share	$ (1.91)	$ (3.09)

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[i] If approved by the FDA