UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2023

Tempest Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35890**	**45-1472564**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Sierra Point Parkway, Suite 400 **Brisbane, California** **(Address of Principal Executive Offices)**	**94005** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (415) 798-8589

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	TPST	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2023, Tempest Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the Company's press release dated May 10, 2023, titled "Tempest Reports First Quarter 2022 Financial Results and Provides Corporate Highlights" is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information (including the exhibit hereto) is being furnished under "Item 2.02 Results of Operations and Financial Condition" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated May 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TEMPEST THERAPEUTICS, INC.

Date: May 10, 2023

By: /s/ Stephen Brady
Name: Stephen Brady
Title: Chief Executive Officer

Tempest Reports First Quarter 2023 Financial Results and Provides Business Update

Brisbane, CA, May 10, 2023 – Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing first-in-class[i] therapeutics that combine both targeted and immune-mediated mechanisms, today reported financial results for the quarter ended March 31, 2023 and provided a corporate update.

“The first few months of 2023 set the pace for what we believe will be a transformative year for Tempest,” said Stephen Brady, chief executive officer of Tempest. “Recently, we announced exciting early data showing that TPST-1120, the company’s PPARα antagonist, combined with standard of care in first-line HCC patients demonstrated clinically meaningful improvement in multiple categories, including RECIST responses, over standard of care alone in an ongoing global randomized Phase 1b/2 study. Additionally, at AACR, we presented data highlighting new translational biomarker findings for TPST-1120, as well as the first-of-its-kind co-crystal structures of human TREX1 enzyme and a TREX1 inhibitor, which we believe is an important step forward towards systemic modulation of the STING pathway. We are excited to continue this momentum with multiple potential catalysts this year and in 2024, including more later-stage and biomarker data from the HCC study with TPST-1120.”

Recent Highlights

- **TPST-1120** (clinical PPARα antagonist): (i) presented new biomarker data from Phase 1 patients at the 2023 American Association for Cancer Research (AACR) Annual Meeting and Society for Immunotherapy of Cancer (SITC) 2023 Spring Scientific Meeting; (ii) disclosed the completion of enrollment in the global randomized first-line Phase 1b/2 study in patients with hepatocellular carcinoma (HCC), under a collaboration with F. Hoffmann La Roche (Roche); and (iii) announced positive early results from the randomized HCC study, demonstrating clinically meaningful improvements in multiple categories and a favorable safety profile when combined with the standard-of-care regimen of atezolizumab and bevacizumab, compared head-to-head to standard-of-care alone, including:

- Unconfirmed responses of 30% for the TPST-1120 triplet arm (12/40) vs. 17.2% for the active control arm (5/29), demonstrating a 74.4% relative improvement in objective response rate (ORR);
- Confirmed responses of 17.5% for the TPST-1120 triplet arm (7/40) vs. 10.3% for the active control arm (3/29), demonstrating a 69.9% relative improvement in confirmed ORR;
- 47.5% (19/40) of the TPST-1120 arm patients are on treatment vs. 23.3% (7/30) in the control arm; and
- 80% (32/40) of the TPST-1120 arm patients are on study vs. 50% (15/30) in the control.[ii]

- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): (i) continued enrollment of a study evaluating combination dose and schedule optimization with the anti-PD-1 checkpoint inhibitor, pembrolizumab; and (ii) enrolled first patient in an endometrial cancer-specific arm investigating the two highest doses of TPST-1495 in combination with pembrolizumab.
- **TREX1 Inhibitor** (preclinical tumor-selective STING pathway activator): presented data, including human TREX1 enzyme—TREX1 inhibitor X-ray co-crystal structures, at the 2023 AACR Annual Meeting.

Potential Upcoming Milestones

- **TPST-1120** (clinical PPARα antagonist): we expect to receive updated data from the ongoing global randomized first-line Phase 1b/2 study in patients with HCC from Roche.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): we plan to report data from (i) the Phase 1 dose and schedule optimization trial studying monotherapy and combination therapy with an anti-PD1 therapy, pembrolizumab, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, and (ii) a separate combination arm at the two highest TPST-1495 doses in patients with advanced endometrial cancer in 2024.
- **TREX1 Inhibitor** (preclinical tumor-selective STING pathway activator): we expect to advance new proprietary small molecule series TREX1 inhibitors generated through insights resulting from human TREX1-inhibitor co-crystal structures.

Financial Results

First Quarter 2023

- Tempest ended the first quarter with $22.9 million in cash and cash equivalents, compared to $31.2 million on December 31, 2022.

- Net loss and net loss per share for the quarter ended March 31, 2023 were $7.6 million and $0.55, respectively, compared to $8.5 million and $1.18, respectively, for the same period in 2022.
- Research and development expenses for the quarter ended March 31, 2023 were $4.7 million compared to $5.1 million for the same period in 2022. The decrease was primarily due to a decrease in research and development costs incurred from contract research organizations and third-party vendors, offset by an increase in personnel costs, as well as facilities expenses.
- General and administrative expenses for the quarter ended March 31, 2023 were $2.9 million compared to $3.1 million for the same period in 2022. The decrease was primarily due to a decrease in consulting and professional services.
- Based on the current cash position and operating plan, Tempest expects to have sufficient resources to fund operations through the second quarter of 2024.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage oncology company advancing small molecules that combine both tumor-targeted and immune-mediated mechanisms with the potential to treat a wide range of tumors. The company has a diverse portfolio of novel programs ranging from early research to investigation in a randomized global study in first-line cancer patients. The company's two clinical programs, TPST-1120 and TPST-1495, target PPARα and EP2/EP4, respectively, and are advancing through trials designed to study the agents as monotherapies and in combination with approved agents. Tempest is also developing an orally available inhibitor of TREX1, a target that controls activation of the cGAS/STING pathway. 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 Tempest Therapeutic's product candidates; the Company's ability to deliver on potential value-creating milestones; the Company's guidance regarding cash runway, as well as our 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 March 31, 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.

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

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 22,925	$ 31,230
Insurance recovery of legal settlement	450	450
Prepaid expenses and other current assets	1,298	1,270
Total current assets	24,673	32,950
Property and equipment, net	1,008	1,060
Operating lease right-of-use assets	11,219	11,650
Other noncurrent assets	429	429
Total assets	$ 37,329	$ 46,089
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,157	$ 1,108
Accrued legal settlement	450	450
Accrued expenses and other	2,538	2,961
Current loan payable, net	1,481	-
Current operating lease liabilities	1,325	1,413
Accrued compensation	456	1,248
Interest payable	104	97
Total current liabilities	7,511	7,277
Loan payable, net	8,935	10,371
Operating lease liabilities	9,918	10,330
Total liabilities	26,364	27,978
Stockholders' equity		
Common stock	11	11
Additional paid-in capital	154,362	153,872
Accumulated deficit	(143,408)	(135,772)
Total stockholders' equity	10,965	18,111
Total liabilities and stockholders' equity	$ 37,329	$ 46,089

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

	Three months ended March 31, 2023	Three months ended March 31, 2022
Expenses:		
Research and development	$ 4,678	$ 5,109
General and administrative	2,903	3,052
Total expenses	7,581	8,161
Operating loss	(7,581)	(8,161)
Other income (expense), net:		
Interest expense	(344)	(333)
Interest and other income, net	289	3
Net loss	$ (7,636)	$ (8,491)
Net loss per share	$ (0.55)	$ (1.18)

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[i] If approved by the FDA
[ii] As of data cutoff date, February 8, 2023