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): August 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	**94005**
(Address of Principal Executive Offices)	**(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 August 10, 2023, Tempest Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. A copy of the Company's press release dated August 10, 2023, titled "Tempest Reports Second Quarter 2023 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 August 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: August 10, 2023

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

Tempest Reports Second Quarter 2023 Financial Results and Provides Business Update

Brisbane, CA, August 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 June 30, 2023 and provided a corporate update.

“2023 continues to be a productive and potentially transformative year for Tempest,” said Stephen Brady, chief executive officer of Tempest. “In the second quarter, we presented data from our second clinical program, TPST-1495, the company’s novel dual EP2/EP4 antagonist designed to selectively modulate the prostaglandin pathway, both at ASCO and in a paper published in Cancer Research Communications. These presentations were made on the heels of announcing early exciting triplet data from our lead TPST-1120 program demonstrating a clinically-meaningful improvement over standard of care alone in first-line HCC patients in an ongoing, global, randomized Phase 1b/2 study. We expect to be able to discuss an updated and comprehensive data set from the formal review of this trial in the second half of 2023.”

Recent Highlights

- **TPST-1120** (clinical PPARα antagonist): announced positive early results from the ongoing randomized first-line HCC study comparing TPST-1120 combined with the standard-of-care regimen of atezolizumab and bevacizumab, with head-to-head to standard-of-care alone. The data were positive in multiple categories, and demonstrated a favorable safety profile:
    - 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) presented data from a Phase 1 study evaluating TPST-1495 as a monotherapy and in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in advanced solid tumors at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; (ii) published mechanism of action data highlighting the increased potency of the molecule against prostaglandin-driven tumor models in *Cancer Research Communications*, a journal of the American Association for Cancer Research; and (iii) continued enrollment of an endometrial cancer-specific arm investigating the two highest doses of TPST-1495 in combination with pembrolizumab.

Potential Upcoming Milestones

- **TPST-1120** (clinical PPARα antagonist): we expect to be able to discuss an updated and comprehensive data set from the formal review of the ongoing, global, randomized Phase 1b/2 study in first-line liver cancer patients in the second half of 2023.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): we plan to report data from the 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

Second Quarter 2023

- Tempest ended the second quarter with $17.6 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 June 30, 2023 were $7.6 million and $0.54, respectively, compared to $9.2 million and $0.79, respectively, for the same period in 2022.
- Research and development expenses for the quarter ended June 30, 2023 were $4.4 million compared to $5.7 million for the same period in 2022. The decrease was primarily due to a decrease in costs incurred from contract research organizations and third-party vendors, partially offset by an increase in personnel costs, as well as facilities expenses.

- General and administrative expenses for the quarter ended June 30, 2023 were $3.1 million. The decrease was primarily due to a decrease in consulting and professional expenses.

Year-to-Date

- Net cash used in operations for the six months ended June 30, 2023 was $14.7 million.
- Net loss and net loss per share for the six months ended June 30, 2023 were $15.2 million and $1.09, respectively, compared to $17.7 million and $1.88, respectively, for the same period in 2022.
- Research and development expenses for the six months ended June 30, 2023 were $9.1 million compared to $10.8 million for the same period in 2022. The $1.7 million decrease was primarily due to a decrease in costs incurred from contract research organizations and third-party vendors, partially offset by an increase in personnel costs, as well as facilities expenses.
- General and administrative expenses for the six months ended June 30, 2023 were $6.0 million compared to $6.2 million for the same period in 2022. The $0.2 million decrease was primarily due to a decrease in consulting and professional expenses.

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 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, 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 17,604	$ 31,230
Insurance recovery of legal settlement	-	450
Prepaid expenses and other current assets	931	1,270
Total current assets	18,535	32,950
Property and equipment, net	1,005	1,060
Operating lease right-of-use assets	10,804	11,650
Other noncurrent assets	398	429
Total assets	$ 30,742	$ 46,089
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 868	$ 1,108
Accrued legal settlement	-	450
Accrued expenses and other	2,454	2,961
Current loan payable, net	2,974	-
Current operating lease liabilities	1,414	1,413
Accrued compensation	823	1,248
Interest payable	105	97
Total current liabilities	8,638	7,277
Loan payable, net	7,484	10,371
Operating lease liabilities	9,608	10,330
Total liabilities	25,730	27,978
Stockholders' equity		
Common stock	13	11
Additional paid-in capital	155,988	153,872
Accumulated deficit	(150,989)	(135,772)
Total stockholders' equity	5,012	18,111
Total liabilities and stockholders' equity	$ 30,742	$ 46,089

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

	Three months ended June 30, 2023	Three months ended June 30, 2022	Six months ended June 30, 2023	Six months ended June 30, 2022
Expenses:				
Research and development	$ 4,416	$ 5,651	$ 9,094	$ 10,760
General and administrative	3,054	3,123	5,957	6,175
Total expenses	7,470	8,774	15,051	16,935
Operating loss	(7,470)	(8,774)	(15,051)	(16,935)
Other income (expense), net:				
Interest expense	(355)	(464)	(699)	(797)
Interest and other income, net	244	70	533	73
Net loss	$ (7,581)	$ (9,168)	$ (15,217)	$ (17,659)
Net loss per share	$ (0.54)	$ (0.79)	$ (1.09)	$ (1.88)

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[i] If approved by the FDA

[ii] As of data cutoff date, February 8, 2023