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 09, 2024

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
Series A Junior Participating Preferred Purchase Rights	N/A	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 9, 2024, Tempest Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024 and other business highlights. A copy of the Company's press release dated May 9, 2024, titled "Tempest Reports First Quarter 2024 Financial Results and Provides Business Update" is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information (including Exhibit 99.1 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, or otherwise subject to the liabilities of that section, 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 9, 2024
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 9, 2024

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

Exhibit 99.1

Tempest Reports First Quarter 2024 Financial Results and Provides Business Update

- *Advancing TPST-1120 into a pivotal Phase 3 trial in first-line HCC and TPST-1495 into a Phase 2 in FAP*
- *Reported new preclinical data for TPST-1120 in kidney cancer at the AACR Annual Meeting*
- *Published positive data from the Phase 1 Trial of TPST-1120 in patients with advanced solid tumors in the Journal of Cancer Research Communications*
- *Presented new data at the SITC 2024 Spring Scientific Meeting elucidating the mechanism of TPST-1120 and supporting its potential in multiple cancers*

Brisbane, CA, May 9, 2024 **–** 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 March 31, 2024, and provided a corporate update.

"The positive data and mechanistic analysis presented in the first quarter build on the positive preclinical and clinical data package for TPST-1120, further confirming and reinforcing our excitement about the potential of TPST-1120 in liver and kidney cancers, as well as other indications, and our confidence in the program as it moves closer to a pivotal Phase 3 study in first-line HCC," said Stephen Brady, president and chief executive officer of Tempest.

Recent Highlights

- **TPST-1120** (clinical PPARα antagonist):
  - Reported new preclinical data at the 2024 American Association for Cancer Research (AACR) Annual Meeting demonstrating that TPST-1120 reduces kidney cancer (RCC) 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 TPST-1120 in patients with advanced solid tumors in the *Journal of Cancer Research Communications*. Data showed that TPST-1120 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 TPST-1120 in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC.
- Presented new preclinical data showing potent anti-tumor activity in several cancer models treated with TPST-1120 alone or with immune checkpoint inhibitors at the Society for Immunotherapy of Cancer (SITC) 2024 Spring Scientific Meeting. The presentation also covered experimental results that corroborated clinical biomarker data from patients with advanced solid tumor cancers treated in the Phase 1 clinical trial of TPST-1120 in multiple solid tumor indications, which showed statistically significant, exposure-dependent elevations in expression levels of multiple immune-related genes, and patients exhibiting objective responses displayed increased circulating free fatty acids (FFA), both of which are in-line with the proposed TPST-1120 mechanism of action.

Potential Future Milestones

- **TPST-1120** (clinical PPARα antagonist)
  - Expect to announce updated data from the ongoing randomized study in first-line HCC patients in 2024.
  - Plan to advance TPST-1120 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

First Quarter 2024

- Tempest ended the quarter with $32.3 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 March 31, 2024, were $7.9 million and $0.36, respectively, compared to $7.6 million and $0.55, respectively, for the same period in 2023.
- Research and development expenses for the quarter were $4.3 million compared to $4.7 million for the same period in 2023. The $0.4 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 quarter were $3.6 million compared to $2.9 million for the same period in 2023. The $0.7 million increase was primarily due to share-based compensation expense and consulting services.
- Based on its current cash and operating plan, Tempest expects 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 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 March 31, 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)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 32,326	$ 39,230
Prepaid expenses and other current assets	1,171	1,133
Total current assets	33,497	40,363
Property and equipment, net	920	840
Operating lease right-of-use assets	9,513	9,952
Other noncurrent assets	448	448
Total assets	$ 44,378	$ 51,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,051	$ 845
Accrued expenses	1,524	1,673
Current loan payable, net	6,458	4,285
Current operating lease liabilities	858	952
Accrued compensation	690	1,543
Interest payable	110	113
Total current liabilities	10,691	9,411
Loan payable, net	4,140	6,264
Operating lease liabilities	8,915	9,160
Total liabilities	23,746	24,835
Stockholders' equity		
Common stock	22	22
Additional paid-in capital	193,777	192,009
Accumulated deficit	(173,167)	(165,263)
Total stockholders' equity	20,632	26,768
Total liabilities and stockholders' equity	$ 44,378	$ 51,603

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

	Three months ended March 31, 2024	Three months ended March 31, 2023
Expenses:		
Research and development	$ 4,340	$ 4,678
General and administrative	3,634	2,903
Operating loss	(7,974)	(7,581)
Other income (expense), net:		
Interest expense	(368)	(344)
Interest and other income, net	438	289
Net loss	$ (7,904)	$ (7,636)
Net loss per share	$ (0.36)	$ (0.55)

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[1] If approved by the FDA