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): November 08, 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
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 November 8, 2023, Tempest Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the Company's press release dated November 8, 2023, titled "Tempest Reports Third 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 November 8, 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: November 8, 2023

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

Tempest Reports Third Quarter 2023 Financial Results and Provides Business Update

- *TPST-1120 demonstrates superiority compared to standard of care across multiple study endpoints in randomized first-line HCC study*
- *New capital strengthens balance sheet and extends cash runway into 2025*

Brisbane, CA, November 8, 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 third quarter ended September 30, 2023 and provided a corporate update.

“We were extremely pleased to see the pronounced external validation of the new data showing the clear 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. “The data have not only improved since the earlier interim analysis, but also include exciting new biomarker results showing that the addition of TPST-1120 effectively rescues the standard of care in PD-L1 negative patients, as well as producing an increased response rate in patients with a b-catenin mutation. Armed with these data and a stronger balance sheet, we are engaged in discussions with potential partners and intend to move TPST-1120 forward in liver cancer, as well as potentially in other indications like kidney cancer given positive signals observed in earlier studies.”

Recent Highlights

- **TPST-1120** (clinical PPARα antagonist): Reported data demonstrating superiority of TPST-1120 across multiple study endpoints in first-line hepatocellular carcinoma. The ongoing randomized trial is evaluating TPST-1120 combined with the standard-of-care regimen of atezolizumab and bevacizumab compared to standard of care alone. 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

- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): Continued enrollment of an endometrial cancer-specific arm investigating the two highest doses of TPST-1495 in combination with pembrolizumab.
- **Stockholder Rights Plan:** Adopted a limited duration stockholder rights plan on October 10, 2023 to enable all Tempest stockholders to realize the long-term value of their investment. The rights plan is intended to reduce the likelihood that any person or group gains control of Tempest through open market accumulation without paying stockholders an appropriate control premium or without providing the Board sufficient time to make informed judgments and take actions that are in the best interests of all stockholders.

Potential Future Milestones

- **TPST-1120** (clinical PPARα antagonist): Plan to advance TPST-1120 into a registrational study in first-line liver cancer patients, likely in connection with a partnership.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): Expect 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): Plan to advance new proprietary small molecule series TREX1 inhibitors generated

through insights resulting from human TREX1-inhibitor co-crystal structures with the goal to select a lead or development candidate by the end of 2023 or early 2024.

Interim Cash Guidance

- As of November 7, 2023, preliminary cash and cash equivalents were $32.8 million, which reflects $23.9 million of net proceeds raised pursuant to the Company's at-the-market (ATM) program. The results for the quarter-to-date period are preliminary, unaudited and are not necessarily indicative of the results that may be expected for the full quarter or year ending December 31, 2023.
- New capital plus the cash and cash equivalents as of the end of the third quarter of 2023 extends the Company's cash runway into 2025.

Financial Results

Third Quarter 2023

- **Cash and cash equivalents** at the end of the third quarter were $11.1 million, compared to $31.2 million on December 31, 2022.
- **Net loss and net loss per share** for the quarter ended September 30, 2023 were $6.8 million and $0.48, respectively, compared to $8.9 million and $0.66, respectively, for the same period in 2022.
- **Research and development expenses** for the quarter ended September 30, 2023 were $4.2 million compared to $6.0 million for the same period in 2022. The $1.8 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 ended September 30, 2023 were $2.4 million compared to $2.8 million for the same period in 2022. The decrease was primarily due to a decrease in consulting and professional expenses and personnel costs.

Year-to-Date

- **Net cash** used in operations for the nine months ended September 30, 2023 was $21.2 million.
- **Net loss and net loss per share** for the nine months ended September 30, 2023 were $22.0 million and $1.57, respectively, compared to $26.6 million and $2.46, respectively, for the same period in 2022.

- **Research and development expenses** for the nine months ended September 30, 2023 were $13.3 million compared to $16.7 million for the same period in 2022. The $3.4 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 facilities expenses.
- **General and administrative expenses** for the nine months ended September 30, 2023 were $8.3 million compared to $9.0 million for the same period in 2022. The $0.7 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 the Company's

product candidates; the Company's ability to deliver on potential value-creating milestones; the Company's ability to achieve its operational plans; the Company's ability to find a suitable partner to develop TPST-1120 in first-line liver cancer patients; and the Company's preliminary cash and cash equivalents as of November 7, 2023. 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 11,118	$ 31,230
Insurance recovery of legal settlement	-	450
Prepaid expenses and other current assets	1,173	1,270
Total current assets	12,291	32,950
Property and equipment, net	921	1,060
Operating lease right-of-use assets	10,382	11,650
Other noncurrent assets	393	429
Total assets	$ 23,987	$ 46,089
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,139	$ 1,108
Accrued legal settlement	-	450
Accrued expenses and other	1,995	2,961
Current loan payable, net	2,134	-
Current operating lease liabilities	1,117	1,413
Accrued compensation	931	1,248
Interest payable	106	97
Total current liabilities	7,422	7,277
Loan payable, net	8,371	10,371
Operating lease liabilities	9,384	10,330
Total liabilities	25,177	27,978
Stockholders' equity		
Common stock	14	11
Additional paid-in capital	156,571	153,872
Accumulated deficit	(157,775)	(135,772)
Total stockholders' equity	(1,190)	18,111
Total liabilities and stockholders' equity	$ 23,987	$ 46,089

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

	Three months ended September 30, 2023	Three months ended September 30, 2022	Nine months ended September 30, 2023	Nine months ended September 30, 2022
Expenses:				
Research and development	$ 4,221	$ 5,973	$ 13,315	$ 16,733
General and administrative	2,371	2,798	8,328	8,973
Total expenses	6,592	8,771	21,643	25,706
Operating loss	(6,592)	(8,771)	(21,643)	(25,706)
Other income (expense), net:				
Interest expense	(373)	(389)	(1,072)	(1,186)
Interest and other income, net	179	213	712	286
Net loss	$ (6,786)	$ (8,947)	$ (22,003)	$ (26,606)
Net loss per share	$ (0.48)	$ (0.66)	$ (1.57)	$ (2.46)

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[1] If approved by the FDA