

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): March 22, 2023

Tempest Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-35890  
(Commission File Number)

45-1472564  
(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 Capital Market

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 March 22, 2023, Tempest Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2022. A copy of the Company’s press release dated March 22, 2023, titled “Tempest Reports Year End 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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release dated March 22, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: March 22, 2023

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

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## Tempest Reports Year End 2022 Financial Results and Provides Business Update

- *Positive monotherapy and combination therapy data from Phase 1 trial of first clinical program, TPST-1120, announced in an oral presentation at ASCO 2022*
- *TPST-1120 randomized combination study in first-line HCC patients with partner Roche is fully enrolled, with initial data expected in the first half of 2023*
- *New data on TPST-1120 biomarker and proprietary small molecule TREX1 inhibitor accepted for presentation at AACR 2023*
- *TPST-1495 Phase 1 monotherapy and combination dose escalation and optimization ongoing, with initial data release planned by mid 2023*

**Brisbane, CA**, March 22, 2023 – Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing first-in-class<sup>1</sup> therapeutics that combine both targeted and immune-mediated mechanisms, today reported financial results for the year ended December 31, 2022 and provided a corporate update.

“2022 featured significant milestones for the company, including our first clinical proof of concept data, which was recognized in an oral presentation at ASCO,” said Stephen Brady, chief executive officer of Tempest. “We were pleased to see TPST-1120 confer clinical benefit to patients, including a 30% ORR at the two highest doses in patients who had not responded to checkpoint inhibitors or who had cancer that doesn’t traditionally respond to immunotherapy. We look forward to data this year from our randomized global study with Roche in first-line liver cancer patients, as well as our second clinical program, TPST-1495, where we’ve observed disease control in late-stage cancer patients, as well as data from our exciting preclinical program targeting TREX1 in the STING pathway. 2023 is shaping up to be a data-rich year for Tempest.”

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<sup>1</sup> If approved by the FDA

**2022 Accomplishments**

- **TPST-1120** (clinical PPAR $\alpha$  antagonist): (i) completed Phase 1 clinical study investigating TPST-1120, as a monotherapy and in combination with an anti-PD1 therapy, nivolumab, and selected recommended Phase 2 dose (“RP2D”); (ii) announced positive results including RECIST responses from the Phase 1 study in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting; (iii) presented data showing pharmacodynamic and predictive biomarkers associated with responses in cancer patients from the Phase 1 study at the 2022 Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting; and (iv) continued enrollment in first-line, randomized global Phase 1b/2 study in patients with hepatocellular carcinoma (HCC), under a collaboration with F. Hoffmann La Roche.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): (i) completed enrollment in a Phase 1 study evaluating monotherapy dose and schedule optimization; (ii) continued enrollment of a study evaluating combination dose and schedule optimization with the anti-PD-1 checkpoint inhibitor, pembrolizumab; and (iii) presented preclinical data showing the superiority of targeting EP2 and EP4 together in comparison to other prostaglandin pathway approaches at both the American Association for Cancer Research (AACR) Annual Meeting 2022 and SITC 2022.
- **TREX1 Inhibitor** (preclinical tumor-selective STING pathway activator): presented the first preclinical anti-tumor results with proprietary small molecule TREX1 inhibitor at AACR 2022.
- **Expansion of Patent Portfolio:** the U.S. Patent and Trademark Office issued a patent covering methods of treatment for our therapeutic product candidate, TPST-1495.

**Planned Near-Term Milestones**

- **TPST-1120** (clinical PPAR $\alpha$  antagonist): we expect to (i) present new data showing an association of RECIST responses and biomarker changes at AACR 2023; and (ii) report objective response data from up to 40 HCC patients in each arm in the first-line randomized study in the first half of 2023.
  - **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): we plan to disclose data from (i) the Phase 1 dose escalation and schedule optimization trial studying monotherapy and combination therapy with an anti-PD1 therapy, pembrolizumab, by mid-2023, and (ii) a separate combination arm at the two highest TPST-1495 doses in patients with advanced endometrial cancer in 2024.
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- **TREX1 Inhibitor** (preclinical tumor-selective STING pathway activator): we expect to present new preclinical anti-tumor results at AACR 2023 with new proprietary small molecule series TREX1 inhibitors generated through insights resulting from human TREX1-inhibitor co-crystal structures.

## Financial Results

### Year End 2022

- Tempest ended the year with \$31.2 million in cash and cash equivalents, compared to \$51.8 million on December 31, 2021. The decrease was primarily due to cash used in operations of \$31.1 million, as well as \$4.7 million repayment of principal on our loan, offset by net proceeds from the issuance of common stock of \$8.9 million and pre-funded warrants of \$7.3 million.
- Net loss and net loss per share for the year were \$35.7 million and \$3.09, respectively, compared to \$28.3 million and \$7.47, respectively, for the same period in 2021.
- Research and development expenses for the year were \$22.5 million compared to \$17.2 million for the same period in 2021. The \$5.3 million increase was primarily attributable to expanded research and development efforts and higher compensation expenses due to an increase in employee headcount.
- General and administrative expenses for the year were 2022 were \$12.1 million compared to \$9.8 million for the same period in 2021. The increase of \$2.3 million was primarily due to professional and consulting fees and insurance expense.
- Based on 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 novel clinical programs, TPST-1120 and TPST-1495, target PPAR $\alpha$  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](http://www.tempesttx.com).

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## 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 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 September 30, 2022 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)

	December 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 31,230	\$ 51,829
Insurance recovery of legal settlement	450	15,000
Prepaid expenses and other current assets	1,270	2,134
Total current assets	32,950	68,963
Property and equipment, net	1,060	1,113
Operating lease right-of-use assets	11,650	3,051
Other noncurrent assets	429	111
Total assets	\$ 46,089	\$ 73,238
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 1,108	\$ 991
Accrued legal settlement	450	15,000
Accrued expenses and other	2,961	1,589
Current operating lease liabilities	1,413	1,442
Accrued compensation	1,248	912
Interest payable	97	92
Total current liabilities	7,277	20,026
Loan payable, net	10,371	15,069
Operating lease liabilities	10,330	2,026
Total liabilities	27,978	37,121
Stockholders' equity		
Common stock	11	7
Additional paid-in capital	153,872	136,173
Accumulated deficit	(135,772)	(100,063)
Total stockholders' equity	18,111	36,117
Total liabilities and stockholders' equity	\$ 46,089	\$ 73,238

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

	Twelve months ended December 31, 2022	Twelve months ended December 31, 2021
<b>Expenses:</b>		
Research and development	\$ 22,527	\$ 17,166
General and administrative	12,113	9,820
Total expenses	<u>34,640</u>	<u>26,986</u>
<b>Operating loss</b>	<u>(34,640)</u>	<u>(26,986)</u>
<b>Other income (expense), net:</b>		
Interest expense	(1,618)	(1,282)
Interest and other income, net	549	(34)
<b>Net loss</b>	<u>\$ (35,709)</u>	<u>\$ (28,302)</u>
<b>Net loss per share</b>	<u>\$ (3.09)</u>	<u>\$ (7.47)</u>

**Investor Contacts:**

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