

**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 12, 2021

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.)

**7000 Shoreline Court, Suite 275
South San Francisco, CA 94080**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (415) 798-8589

N/A
(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 (see General Instruction A.2. below):

- 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, par value \$0.001 per share	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 August 12, 2021, Tempest Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second fiscal quarter ended June 30, 2021. A copy of the Company’s press release dated August 12, 2021, titled “Tempest Reports Second Quarter 2021 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 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers

Appointment of Directors

Effective as of August 6, 2021, the Company’s Board of Directors (the “Board”) appointed Ronit Simantov, M.D. to serve as Class III director of the Board. Class III directors serve until the 2024 annual meeting of stockholders. There is no arrangement or understanding between Dr. Simantov and us, or any other person, pursuant to which she was appointed as a director.

Dr. Simantov will receive compensation consistent with the Company’s Non-Employee Director Compensation Policy (the “Non-Employee Director Compensation Policy”), which provides for annual cash compensation of \$40,000 for service on the Board. In addition, pursuant to the Non-Employee Director Compensation Policy, Dr. Simantov (a) was granted an option to purchase 6,635 shares of the Company’s common stock, pursuant to which one third of the shares subject to the option will vest on the one-year anniversary of the date of grant and the remaining two thirds will vest in equal monthly installments over the 24 months thereafter, and (b) will be granted an option to purchase 3,318 shares of the Company’s common stock following each annual meeting of stockholders commencing with the 2022 annual meeting of stockholders, pursuant to which 100% of the shares subject to the option will vest on the earlier of (i) one-year anniversary of the date of grant or (ii) the date of the Company’s annual meeting of stockholders for the year subsequent to the year such grant is made. Further, Dr. Simantov will enter into the Company’s standard form of indemnification agreement providing for indemnification, subject to certain limitations, by the Company in connection with her service as a director of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

TEMPEST THERAPEUTICS, INC.

Date: August 12, 2021

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



**Tempest Reports Second Quarter 2021 Financial Results and
Provides Corporate Highlights**

- *Closed merger transaction resulting in public listing (TPST)*
- *Closed \$30M PIPE, extending runway into Q1'23*
- *Advancing TPST-1495 and TPST-1120 into targeted patient populations*
- *Advanced TREX-1 program to potent lead series with in vivo efficacy*

South San Francisco, CA, August 12, 2021 – Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing potentially first-in-class therapeutics that combine both targeted and immune-mediated mechanisms, today reported financial results and provided a corporate update for the second quarter ended June 30, 2021.

“The second quarter of 2021 was an exciting period as Tempest became a public company and the team drove progress in all three of our novel programs,” said Steve Brady, chief executive officer of Tempest. “We look forward to the planned opening of the TPST-1120 randomized study in first line hepatocellular carcinoma in collaboration with Roche and the first combination study of TPST-1495, and remain focused on delivering potentially value-creating milestones over the next year and beyond.”

Recent Highlights

- **Public Company Transition:** successfully closed merger and concurrent PIPE financing, allowing Tempest to become a public company listed on the Nasdaq Capital Market, and extending runway into 2023 through multiple potential catalysts.
- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): continued enrollment in monotherapy dose optimization towards recommended Phase 2 dose (“RP2D”).
- **TPST-1120** (clinical PPAR α antagonist): (i) completed monotherapy dose escalation and selected 600mg BID as RP2D; (ii) observed stable disease (“SD”) in 50% of the monotherapy-treated patients, including prolonged SD in patients with refractory cholangiocarcinoma; and (iii) observed a deep, confirmed partial response in a patient with checkpoint inhibitor-refractory fourth line renal cell carcinoma in the combination study with nivolumab (~60% by RECIST 1.1, durable through 4 scans and ongoing).

- **TREX-1 Inhibitor** (preclinical, tumor-selective STING pathway activator): (i) progressed lead series to picomolar IC₅₀ potency in biochemical assays; and (ii) demonstrated significant proof of concept in a mouse tumor model with systemic delivery of a lead series molecule.
- **Board of Directors:** Christine Pellizzari, J.D., Geoff Nichol, M.B., Ch.B., M.B.A., and Ronit Simantov, M.D., joined the Board of Directors, bringing deeper financial, legal, and clinical development expertise to Tempest.

Planned Near-Term Milestones

- **TPST-1495** (clinical dual EP2/4 prostaglandin receptor antagonist): (i) selection of monotherapy RP2D expected in the first half of 2022; (ii) commencement of a combination study with an anti-PD-1 checkpoint inhibitor expected prior to the end of 2021; and (iii) commencement of monotherapy expansion in targeted indications and biomarker-selected patient populations expected in the first half of 2022.
- **TPST-1120** (clinical PPAR α antagonist): (i) identification of RP2D of TPST-1120 in combination with nivolumab expected prior to the end of 2021; and (ii) commencement of first line randomized Phase 1b/2 study in hepatocellular carcinoma patients, under a collaboration with F. Hoffman La Roche, expected within the third quarter.
- **TREX-1 Inhibitor** (preclinical tumor-selective STING pathway activator): planned selection of development candidate in the first half of 2022.

Financial Results

Second Quarter

- Tempest ended the second quarter of 2021 with \$68.5 million in cash and cash equivalents and short-term restricted cash, compared to \$18.8 million in December 31, 2020. The increase was primarily due to the merger and concurrent PIPE, which closed in June 2021.
- Net loss and net loss per share for the second quarter of 2021 were \$7.1 million and \$7.63, respectively, compared to \$5.2 million and \$11.42, respectively, for the second quarter of 2020. The increase was primarily due to an increase in compensation expense and professional fees associated with the merger.

- Research and development expenses for the second quarter of 2021 were \$4.2 million, compared to \$4.1 million for the same period in 2020. The \$0.1 million increase was primarily attributable to increased compensation expenses.
- For the three months ended June 30, 2021, general and administrative expenses were \$2.6 million compared to \$1.1 million for the same period in 2020. The increase was primarily due to growth in compensation expense and professional fees associated with the merger.

Year-to-Date

- Net cash used in operations for the six months ended June 30, 2021 was \$6.2 million.
- Net loss and net loss per share for the six months ended June 30, 2021 were \$12.4 million and \$17.30, respectively, compared to \$9.5 million and \$21.28, respectively, for the same period in 2020.
- Research and development expenses for the six months ended June 30, 2021 were \$7.8 million compared to \$7.1 million for the same period in 2020. The \$0.7 million increase was primarily due to increased compensation expenses and consulting services.
- For the six months ended June 30, 2021, general and administrative expenses were \$4.1 million compared to \$2.4 million for the same period in 2020.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage oncology company advancing small molecules that combine both targeted and immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's two novel clinical programs are TPST-1495 and TPST-1120, antagonists of EP2/EP4 and PPAR δ , respectively. Both TPST-1495 and TPST-1120 are advancing through Phase 1 studies designed to study both agents as monotherapies and in combination with other approved agents. Tempest is also developing an orally-available inhibitor of TREX-1 designed to activate selectively the cGAS/STING pathway, an innate immune response pathway important for the development of anti-tumor immunity. Tempest is headquartered in South San Francisco. 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. (“Tempest Therapeutics”). 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 timing and selection of development candidates, dose selection or commencement of, or availability of data from, clinical trials, the company’s guidance regarding cash resources as well as our operational plans and the timing and ability to deliver on value-creating milestones. Forward-looking statements are based on information available to Tempest Therapeutics as of the date hereof and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement. These and other risks are described in greater detail in the Form 10-Q filed by Tempest Therapeutics with the Securities and Exchange Commission on August 12, 2021. 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, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 68,458	\$ 18,820
Prepaid expenses and other current assets	2,036	1,005
Total current assets	<u>70,494</u>	<u>19,825</u>
Property and equipment, net	1,218	1,110
Operating lease right-of-use assets	3,673	1,877
Other noncurrent assets	112	51
Total assets	<u>\$ 75,497</u>	<u>\$ 22,863</u>
Liabilities and Stockholders’ Equity		
Current liabilities		
Accounts payable	\$ 6,695	\$ 1,071
Accrued expenses and other	1,526	1,439
Current operating lease liabilities	1,484	712
Interest payable	89	—
Total current liabilities	<u>9,794</u>	<u>3,222</u>
Loan payable, net	14,915	—
Operating lease liabilities	2,674	1,727
Total liabilities	<u>27,383</u>	<u>4,949</u>
Convertible preferred stock	—	86,707
Stockholders’ equity		
Common stock	7	15
Additional paid-in capital	132,281	2,953
Accumulated deficit	(84,174)	(71,761)
Total stockholders’ equity	<u>48,114</u>	<u>(68,793)</u>
Total liabilities, convertible preferred stock and stockholders’ equity	<u>\$ 75,497</u>	<u>\$ 22,863</u>

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

	Three months ended June 30, 2021	Three months ended June 30, 2020	Six months ended June 30, 2021	Six months ended June 30, 2020
Expenses:				
Research and development	\$ 4,229	\$ 4,094	\$ 7,821	\$ 7,121
General and administrative	2,556	1,144	4,091	2,420
Total expenses	<u>6,785</u>	<u>5,238</u>	<u>11,912</u>	<u>9,541</u>
Operating loss	<u>(6,785)</u>	<u>(5,238)</u>	<u>(11,912)</u>	<u>(9,541)</u>
Other income (expense), net:				
Interest expense	(276)	—	(507)	—
Interest and other income, net	3	9	6	84
Net loss	<u>\$ (7,058)</u>	<u>\$ (5,229)</u>	<u>\$ (12,413)</u>	<u>\$ (9,457)</u>
Net loss per share	<u>\$ (7.63)</u>	<u>\$ (11.42)</u>	<u>\$ (17.30)</u>	<u>\$ (21.28)</u>

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