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): June 1, 2023

Molecular Templates, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-32979**	**94-3409596**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

9301 Amberglen Blvd, Suite 100
Austin, Texas 78729
(Address of Principal Executive Offices) (Zip Code)

(512) 869-1555
(Registrant's telephone number, including area code)

(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	MTEM	The Nasdaq Global Select 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 8.01. Other Events.

On June 1, 2023, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 8.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 8.01 and in the press release furnished as Exhibit 99.1 to this current report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

99.1	Press Release dated June 1, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Molecular Templates, Inc.

Date: June 1, 2023

By: /s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.
Chief Executive Officer

EXHIBIT 99.1

Molecular Templates Announces the FDA Removal of Partial Clinical Hold in the Phase 1 Clinical Trial for MT-0169 and Focuses on Extramedullary Myeloma

AUSTIN, Texas, June 01, 2023 (GLOBE NEWSWIRE) -- Molecular Templates, Inc. (Nasdaq: MTEM, "Molecular Templates," or "MTEM"), a clinical-stage biopharmaceutical company focused on the discovery and development of proprietary targeted biologic therapeutics, engineered toxin bodies ("ETBs"), to create novel therapies with potent differentiated mechanisms of action for cancer, announced today that the U.S. Food and Drug Administration ("FDA"), after reviewing safety data on the program, has removed the partial clinical hold on patient enrollment for its MT-0169 trial, allowing Molecular Templates to proceed with its plan to evaluate the efficacy of MT-0169, one of its ETBs, which specifically targets CD38, a validated target in Multiple Myeloma. The FDA placed the Phase I study for MT-0169 on a partial clinical hold in April 2023, based on previously disclosed asymptomatic and fully reversible cardiac adverse events ("AEs") noted in two patients dosed at 50 mcg/kg which prompted the dose reduction to 5 mcg/kg last year.

"We are pleased that the FDA has removed the partial clinical hold," said Eric Poma, Ph.D., Chief Executive and Chief Scientific Officer of MTEM. "MT-0169 represents a novel approach to myeloma that is demonstrating good safety with early signs of potential clinical benefit, particularly in the extramedullary setting, where we have seen a stringent Complete Response in a patient who remains on study for 10 months."

MTEM will be focusing development of MT-0169 on extramedullary myeloma, a form of myeloma that is less responsive to current therapies and carries a worse overall prognosis. Up to 20% of patients with relapsed/refractory multiple myeloma have extramedullary disease.

About MT-0169

MT-0169 was designed to destroy CD38+ tumor cells through internalization of CD38 and cell destruction via a novel mechanism of action (enzymatic ribosomal destruction and immunogenic cell death). The MT-0169 study completed the 5 mcg/kg dose escalation cohort (N=4) and the 10 mcg/kg dose escalation cohort (N=3) without any cardiac AEs or dose-limiting toxicities. A stringent Complete Response was seen in a patient with extramedullary IgA myeloma dosed with MT-0169 at 5 mcg/kg. The patient had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative, and resolution of uptake on bone scan of skeletal lesions. The patient's disease was quad-agent refractory including CD38-targeting, proteosome inhibitor, IMiD, and a BCMA bispecific antibody. The patient continues on study for 10 months. To date, no instances of capillary leak syndrome or other manifestations of innate immunity have been observed with any next-generation ETB.

About Molecular Templates

Molecular Templates is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted biologic therapeutics. Our proprietary drug platform technology, known as engineered toxin bodies, or ETBs, leverages the resident biology of a genetically engineered form of Shiga-like Toxin A subunit to create novel therapies with potent and differentiated mechanisms of action for cancer.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Molecular Templates disclaims any intent or obligation to update these forward-looking statements and claims the protection of the Act's Safe Harbor for forward-looking statements. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Molecular Templates may identify forward-looking statements. Examples of such statements include but are not limited to the safety or potential efficacy of Molecular Templates' drug or biologic candidates; Molecular Templates' belief that its proprietary biologic drug platform technology, or ETBs, provides for a differentiated mechanism of action for cancer; and the prospects for continued clinical development and regulatory approval. Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors including, but not limited to the following: the uncertainties inherent in the preclinical and clinical development process, including the fact that interim results may not be indicative of future results; whether Molecular Templates' cash resources, will be sufficient to fund its continuing operations for the periods and/or trials anticipated; Molecular Templates' ability to timely enroll patients in its clinical trials; the ability of Molecular Templates' to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Molecular Templates' filings with the Securities and Exchange Commission. There can be no assurance that any of Molecular Templates' drug or biologic candidates will be successfully developed, manufactured, or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Any forward-looking statements contained in this press release speak only as of the date hereof, and Molecular Templates specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

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