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): February 17, 2021

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)**	**(IRS Employer Identification No.)**

9301 Amberglen Blvd, Suite 100
Austin, TX 78729
(Address of principal executive offices and zip code)

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

(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 obligations 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 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 8.01. Other Events.

On February 17, 2021, Molecular Templates, Inc. (the "Company") filed a preliminary prospectus supplement with the Securities and Exchange Commission under its effective shelf registration statement on Form S-3 (Registration No. 333-242078) (the "Preliminary Prospectus Supplement") in connection with a proposed registered underwritten public offering of common stock.

The Preliminary Prospectus Supplement contains information relating to recent developments concerning the Company's business and includes the following disclosure:

Recent Developments

Collaboration Agreement

On February 10, 2021, we entered into a Collaboration Agreement (the "Collaboration Agreement") with Bristol Myers Squibb Company ("Bristol Myers Squibb"), pursuant to which we and Bristol Myers Squibb agreed to enter into a strategic research collaboration to leverage our ETB technology platform to discover and develop novel products containing ETBs directed to multiple targets.

Pursuant to the terms of the Collaboration Agreement, we granted Bristol Myers Squibb a series of exclusive options to obtain one or more exclusive licenses under our intellectual property to exploit products containing ETBs directed against certain targets designated by Bristol Myers Squibb.

Pursuant to the Collaboration Agreement, Bristol Myers Squibb will pay us an upfront payment of $70 million. In addition to the upfront payment, we may receive near term and development and regulatory milestone payments of up to $874.5 million. We will also be eligible to receive up to an additional $450 million in payments upon the achievement of certain sales milestones, and subject to certain reductions, tiered royalties ranging from mid-single digits up to mid-teens as percentages of calendar year net sales, if any, on any licensed product.

We will be responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise of its option for a development candidate, Bristol Myers Squibb will be responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate, subject to the terms and conditions of the Collaboration Agreement.

Unless earlier terminated, the Collaboration Agreement will expire (i) on acountry-by-country basis and licensed product-by-licensed product basis, on the date of expiration of the royalty payment obligations under the Collaboration Agreement with respect to such licensed product in such country and (ii) in its entirety upon the earlier of (a) the expiration of the royalty payment obligations under the Collaboration Agreement with respect to all licensed products in all countries or (b) upon Bristol Myers Squibb's decision not to exercise any option on or prior to the applicable option deadlines. Bristol Myers Squibb has the right to terminate the Collaboration Agreement for convenience upon prior written notice to us. Either party has the right to terminate the Collaboration Agreement (a) for the insolvency of the other party or (b) subject to specified cure periods, in the event of the other party's uncured material breach. We have the right upon prior written notice to terminate the Collaboration Agreement in the event that Bristol Myers Squibb or any of its affiliates asserts a challenge against our patents.

Update on MT-3724 Partial Clinical Hold and Potential Acceleration of Next-Gen CD20 ETB

As previously disclosed, since November 4, 2020, our MT-3724 clinical studies have been on partial clinical hold as ordered by the U.S. Food and Drug Administration ("FDA") following a treatment-related fatality in one subject who experienced Grade 5 capillary leak syndrome ("CLS") in the Phase 2 MT-3724 monotherapy study. At such time, subjects already enrolled in MT-3724 clinical studies who were receiving clinical benefit were permitted to continue dosing but no new patients have been, or will be, enrolled in any MT-3724 study pending resolution of this matter. This partial hold has not resulted in any changes to our trials or plans for our other ETB product candidates, including MT-5111, TAK-169, and MT-6402, all of which utilize a next-generation ETB scaffold that has been designed to reduce or eliminate the propensity for innate immunity, including CLS. To date, we have observed no cases of CLS (any grade) in human subjects who have been dosed with MT-5111. We cannot comment on clinical data from the TAK-169 Phase I study due to confidentiality obligations. We do not yet have clinical data with MT-6402 as the Phase I study of MT-6402 is expected to be initiated in the first half of 2021. As part of our overall investigation into the partial hold on MT-3724, we conducted an investigation into MT-3724 product attributes, and based on our findings, we will propose to implement new drug product manufacturing and release criteria in our partial hold response to FDA. We have determined that the MT-3724 product that has been manufactured to date for use in the MT-3724 studies we plan to continue will not be consistent with the new criteria once it is implemented. Based upon our findings to date and after a thorough risk/benefit assessment, we have decided to discontinue dosing of subjects remaining on our Phase II combination study with MT-3724 and Revlimid® (lenalidomide). Additionally, following our decision to temporarily discontinue dosing for the remaining subject on our Phase II combination study with MT-3724 and chemotherapy (gemcitabine and oxaliplatin, or GemOx), the subject decided in collaboration with their physician to discontinue treatment. Although there have been no signs of capillary leak syndrome toxicity worse than grade 2 in either of these MT-3724 studies, our decision to discontinue dosing in these studies was taken out of an abundance of caution with the study subjects' health and safety in mind. Further, after a review of the current competitive landscape and following the last subject discontinuing treatment,

we have decided to discontinue our Phase II combination study with MT-3724 and chemotherapy (gemcitabine and oxaliplatin, or GemOx). We made this decision based upon our belief in the potential for more promising future combinations with our product candidates. Accordingly, there are currently no subjects being treated under any MT-3724 protocol. In connection with our other MT-3724 studies, we continue to work towards addressing the partial clinical hold and MT-3724 product lot information requests from the FDA and will then seek agreement from FDA to remove the partial clinical hold. There can be no assurance with respect to our ability to remove the partial clinical hold, or the timing thereof. As we undertake these efforts, we are also actively evaluating whether to resume development of MT-3724 or discontinue the MT-3724 program in favor of accelerating the development of a next-generation CD20-targeted ETB or other program in addition to funding the development of our clinical stage next-generation ETB programs, including MT-5111, TAK-169, and MT-6402.

MT-6402—FDA Acceptance of IND Application

On January 19, 2021, we announced that the FDA accepted our Investigational New Drug ("IND") application for MT-6402, a next-generation ETB enabled with antigen seeding targeting PD-L1. We expect to start dosing enrolled subjects in a Phase 1 study in relapsed/refractory patients with PD-L1 positive solid tumors in the second quarter of 2021. The Phase 1 study is planned as a multi-center, open-label, dose escalation and dose expansion trial in the United States and outside of the United States. Patients with confirmed PD-L1-expressing tumors or confirmed PD-L1 expression in the tumor microenvironment will be eligible to screen for enrollment in the clinical trial. Following determination of the maximum tolerated dose ("MTD") or recommended Phase 2 dose, expansion cohorts are planned to study MT-6402 as a monotherapy in tumor-specific and tumor-agnostic cohorts.

Update on MT-5111 Phase 1 Study—Dose Escalation Ongoing in All HER2 Positive Tumor Types

In December 2020, we provided an update on our ongoing Phase 1 study based upon data as of October 2, 2020 for MT-5111, our HER2-targeted ETB. MT-5111 appears to be well tolerated with no dose limiting toxicities ("DLTs") observed in any cohort. In particular, no signs of cardiotoxicity have been observed to date, while monitoring the subjects' EKGs, troponin values and pro-BNP with each treatment, and serial echocardiograms with every other cycle. The most commonly reported adverse events ("AEs") that may be related to MT-5111 among the four dosing cohorts and for which source-verified data were available were: fatigue (n=3), AST increased (n=2) at 0.5 µg/kg and 1 µg/kg, and chills (n=2). These most commonly reported AEs were all of grade 1 or 2 severity. No cases of CLS (any grade) were observed.

Cohort 6 (6.75 µg/kg) is now open for enrollment with cohort 7 (10 µg/kg) expected to open in the first quarter of 2021. The HER2-positive breast cancer expansion cohort is planned to be initiated in the first half of 2021 at a dose of 10 µg/kg (anticipated to be a therapeutic dose level), pending adequate safety data. Dose escalation will continue to determine the Recommended Phase 2 Dose while the breast cancer expansion cohort collects efficacy and safety data. We expect to provide an update on results from the subject currently on treatment as well as higher dose cohorts from the dose escalation portion of the Phase 1 study in the first half of 2021.

Updated Cash Position and Cash Runway Statement

We estimate that, as of December 31, 2020, we had approximately $93.9 million of cash, cash equivalents and marketable securities. This amount is unaudited and preliminary, is subject to completion of financial closing and review procedures that could result in changes to the amount, and does not present all information necessary for an understanding of our financial condition as of December 31, 2020. The preliminary financial data included in this prospectus supplement is based on information available to management as of the date of this prospectus supplement and is subject to completion by management of our financial statements as of and for the quarter ended December 31, 2020. Complete results will be included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Including the upfront payment from our entry into the Collaboration Agreement described above, but not including any proceeds from this proposed offering, we expect that our existing cash and cash equivalents are sufficient to fund our operating expenses and capital expenditure requirements through 2022. For an estimate of our cash runway inclusive of the expected proceeds from this proposed offering, see "*Use of Proceeds*".

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.

Date: February 17, 2021

Molecular Templates, Inc.

By: /s/ Eric E. Poma, Ph.D.
Name: Eric E. Poma, Ph.D
Title: Chief Executive Officer and Chief Scientific Officer