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 5, 2020

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 Per Share	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 2.02. Results of Operations and Financial Condition.

On November 5, 2020, Molecular Templates, Inc. (the "Company") announced its financial results for the third quarter of 2020 ended September 30, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 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 2.02 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.

Exhibit 99.1	Press Release dated November 5, 2020
Exhibit 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: November 5, 2020

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

EXHIBIT 99.1

Molecular Templates, Inc. Reports Third Quarter 2020 Financial Results and Provides a Corporate Update

AUSTIN, Texas, Nov. 05, 2020 (GLOBE NEWSWIRE) -- Molecular Templates, Inc. (Nasdaq: MTEM, "Molecular Templates," "MTEM" or "the Company"), a clinical-stage biopharmaceutical company focused on the discovery and development of proprietary targeted biologic therapeutics, engineered toxin bodies (ETBs), today reported financial results for the third quarter of 2020 and an update on its clinical pipeline.

On November 4, 2020, the U.S. Food and Drug Administration (FDA) notified MTEM that MT-3724 clinical studies have been placed on partial clinical hold following a treatment-related fatality in one subject who experienced Grade 5 capillary leak syndrome (CLS) in the Phase 2 MT-3724 monotherapy study. This subject and four others in the Phase 2 monotherapy study who were treated with material from the same MT-3724 product lot had markedly higher than expected peak drug exposure (C_{max}). Subjects already enrolled in MT-3724 clinical studies will continue to be dosed but no new patients will be enrolled until the partial hold is removed. There are no changes to the trials or plans for 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.

"We are saddened to report the patient death in our MT-3724 monotherapy study. We are committed to working with the FDA to fulfill their information requests, resolve the partial clinical hold, and to resume enrollment of the affected MT-3724 clinical trials as quickly as possible," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Chief Scientific Officer. "In the meantime, our other ETB programs, which are built on our proprietary, next generation de-immunized toxin scaffold with a simplified manufacturing process, are continuing as planned with study updates expected in late 2020 and into 2021."

Company Highlights, Pipeline Status, and Upcoming Milestones

MT-3724 (CD20 ETB)

- The FDA has placed MT-3724 clinical studies on partial clinical hold pending further review of a treatment-related fatality in a single subject in the Phase 2 monotherapy study. Additional information on this subject is detailed below. The FDA has requested additional information around the event, a safety assessment of all data relevant to CLS, as well as additional information assessing attributes of the MT-3724 product lot in question that could have contributed to the high PK values observed.
- The subject that experienced the Grade 5 CLS is one of five subjects in the monotherapy study with elevated pharmacokinetic (PK) findings, all of whom were treated with the same lot of MT-3724. An investigation is underway to determine the cause of the elevated PK in these subjects.
- Until the partial clinical hold is removed, no new subjects will be enrolled in any MT-3724 study but patients currently receiving treatment and who are receiving clinical benefit may continue to be dosed.
- As previously reported, in both Phase 2 combination studies, responses have been observed at MT-3724 doses (10 and 25 µg/kg) considerably lower than the dose used in the Phase 2 monotherapy study (50 µg/kg).
- MTEM will provide an update on the status of the MT-3724 partial clinical hold and future MT-3724 development plans as soon as possible.

TAK-169 (CD38 ETB)

- Takeda and MTEM are conducting an ongoing Phase 1 study evaluating TAK-169 in relapsed/refractory multiple myeloma. This study, which had started dosing in February, had a temporary pause in the activation of new study sites and new patient enrollment (along with most of Takeda's other early stage studies) due to COVID-19 and was recently re-initiated.
- Preclinical data on TAK-169 will be presented at the 62nd ASH Annual Meeting and Exposition being held virtually on December 5-8, 2020.

MT-5111 (HER2 ETB)

- MTEM is conducting a Phase 1 study of MT-5111 in relapsed/refractory HER2-positive cancers.
- Further to the interim update provided in June 2020, MTEM expects to provide an update on results from the dose escalation portion of the Phase 1 study in 4Q20.

Research

- MTEM expects to file an investigational new drug (IND) application in 4Q20 for MT-6402, its ETB targeting PD-L1 (with antigen seeding). A Phase 1 study in relapsed/refractory patients with PD-L1 expressing tumors is expected to be initiated in 1H21.
- MTEM expects to file an IND application for its ETB targeting CTLA-4 in 2021.

COVID-19 Impact

- The COVID-19 pandemic has resulted in a significant slowdown in the pace of site initiations and patient enrollment across our MT-3724 Phase 2 programs. As with other sponsors with studies in patients with hematologic malignancies, we are working with sites to determine when a patient is suitable for each research study and to ensure the continued safety of all research participants.
- To date, screening and enrollment for the MT-5111 Phase 1 study has been less adversely affected than the MT-3724 studies but it is enrolling at a slower pace than was projected pre-COVID-19.
- To date, MTEM has continued to operate its cGMP manufacturing facility and laboratories without interruption from COVID-19. As a

result, manufacturing of product supply for clinical trials and research activities to support advancement of our preclinical pipeline (including partnered programs) have not been adversely affected by COVID-19 to date.

Details on MT-3724 Update

On November 4, 2020, the FDA notified MTEM that MT-3724 clinical studies have been placed on partial clinical hold following a fatality in one subject in the Phase 2 monotherapy study due to treatment-related capillary leak syndrome (CLS) on October 20, 2020. The fatality occurred in a diffuse large B-cell lymphoma (DLBCL) subject who had been treated with six prior lines of therapy including rapid progression through three lines of therapy in the six months prior to MT-3724 dosing (including most recently a first generation anti-CD19 CAR T-cell). The subject had transformed DLBCL from Waldenstrom's Macroglobulinemia and came onto the MT-3724 study with a CD4/CD8 T-cell ratio of 0.47. The subject did not have a radiographic assessment of response but an elevated LDH was thought by the principal investigator to represent disease progression. The subject initially had Grade 2 CLS following treatment with MT-3724, recovered after a dosing interruption, resumed dosing and then had CLS that was ultimately fatal. While Grade 1 and 2 CLS is an expected potential adverse reaction of MT-3724, this was the only subject in any MT-3724 study to date with CLS that was more severe than Grade 2.

In addition, markedly higher than expected peak drug exposure (C_{max}) was observed in five of the last six subjects enrolled in the monotherapy study, including the subject with the fatal CLS. All of these subjects had been treated with drug product from the same lot of MT-3724 and while the other four subjects with higher than predicted exposure exhibited signs or symptoms of innate immunity, none experienced any unexpected serious adverse events. This lot of drug product met all specifications for drug product release as well as its ongoing stability testing specifications. MTEM is investigating the higher than expected drug exposure findings to determine if this was caused by an issue with this specific lot of MT-3724.

MTEM is working to address the clinical and MT-3724 product lot information requests from the FDA and will then seek agreement from FDA to remove the partial clinical hold. In the meantime, no new patients will be enrolled in any MT-3724 study. MTEM's trials and plans for its other ETB product candidates, including MT-5111, TAK-169, and MT-6402, which utilize next-generation ETB technology, are not affected. Next-generation ETB scaffolds have been designed to reduce or eliminate the propensity for innate immunity or CLS; no cases of CLS have been observed in human subjects who have been dosed with any next-generation ETBs.

Financial Results

The net loss attributable to common shareholders for the third quarter of 2020 was $23.2 million, or $0.47 per basic and diluted share. This compares with a net loss attributable to common shareholders of $38.2 million, or $1.03 per basic and diluted share, for the same period in 2019.

Revenues for the third quarter of 2020 were $4.3 million, compared to $3.6 million for the same period in 2019. Revenues for the third quarter of 2020 were comprised of revenues from collaborative research and development agreements with Takeda and Vertex. Total research and development expenses for the third quarter of 2020 were $19.6 million, compared with $15.2 million for the same period in 2019. Total general and administrative expenses for the third quarter of 2020 were $7.5 million, compared with $4.5 million for the same period in 2019.

As of September 30, 2020, MTEM's cash and investments totaled $118.2 million, which is expected to fund operations into 2H22.

About Molecular Templates

Molecular Templates is a clinical-stage 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 and other serious diseases.

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, statements relating to the potential lifting of the partial clinical hold on the Company's MT-3724 clinical trials, our investigation into our pharmacokinetic findings in our MT-3724 monotherapy study and potential plans for our MT-3724 studies, statements regarding the safety or potential efficacy of the Company's drug or biologic candidates, statements relating to the development of the MT-3724, MT-5111, TAK-169, and MT-6402; our utilization of a next-generation ETB scaffold that has been designed to reduce or eliminate the propensity for innate immunity, including CLS; the expected timing of submitting various IND applications and conducting studies; the expected participation and presentation at upcoming medical conferences; the anticipated effects of the COVID-19 pandemic on the Company's ongoing clinical studies, manufacturing and preclinical development; and the Company's belief that its proprietary biologic drug platform technology, or ETBs, provides for a differentiated mechanism of action that may address some of the limitations associated with currently available cancer therapeutics.

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 risks associated with the Company's ability to satisfactorily respond to requests from the FDA for further information and data regarding MT-3724 on the timeline expected or at all; successfully resolve the partial clinical hold with regard to MT-3724; the uncertainties inherent in the preclinical

and clinical development process; whether the Company's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; the ability of the Company to protect its intellectual property rights; risks from global pandemics including COVID-19; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in the Company's filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

Contact:

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Molecular Templates, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Research and development revenue, related party	$ 1,566	$ 2,903	$ 4,962	$ 14,527
Research and development revenue, other	2,732	284	7,176	284
Grant revenue	—	431	3,210	1,262
Total revenue	4,298	3,618	15,348	16,073
Operating expenses:				
Research and development	19,622	15,249	70,667	33,946
General and administrative	7,547	4,509	19,606	14,049
Loss on impairment of in-process research and development	—	22,123	—	22,123
Total operating expenses	27,169	41,881	90,273	70,118
Loss from operations	22,871	38,263	74,925	54,045
Interest and other income, net	167	396	925	1,449
Interest and other expense, net	(521)	(353)	(1,229)	(947)
Loss on extinguishment of debt	—	—	(1,237)	—
Change in fair value of warrant liabilities	—	1	—	3
Loss before provision for income taxes	23,225	38,219	76,466	53,540
Provision for income taxes	—	—	5	—
Net loss	23,225	38,219	76,471	53,540
Net loss attributable to common shareholders	$ 23,225	$ 38,219	$ 76,471	$ 53,540
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 0.47	$ 1.03	$ 1.63	$ 1.45
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	49,026,499	36,937,912	46,808,437	36,832,966

Molecular Templates, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,410	$ 85,451
Marketable securities, current	82,816	39,633
Prepaid expenses	4,889	2,318

Grants revenue receivable	3,490	7,100
Accounts receivable, related party	301	408
In-process research and development - held for sale	4,500	4,500
Other current assets	249	489
Total current assets	129,655	139,899
Marketable securities, non-current	2,000	1,510
Operating lease right-of-use assets, non-current	11,589	9,959
Property and equipment, net	20,889	18,158
Other assets	5,244	4,676
Total assets	$ 169,377	$ 174,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,565	$ 1,465
Accrued liabilities	13,231	14,544
Deferred revenue, current	12,496	8,511
Deferred revenue, current, related party	4,566	8,780
Other current liabilities, related party	5,498	—
Other current liabilities	2,041	2,501
Total current liabilities	40,397	35,801
Deferred revenue, long-term	7,785	18,944
Deferred revenue, long-term, related party	935	441
Long-term debt, net	14,822	2,940
Operating lease liabilities, non-current	12,828	11,682
Other liabilities, related party	6,711	—
Other liabilities	1,458	1,366
Total liabilities	84,936	71,174
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at September 30, 2020 and December 31, 2019; issued and outstanding: 250 shares at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares at September 30, 2020 and December 31, 2019; issued and outstanding: 49,963,732 shares at September 30, 2020 and 45,589,157 shares at December 31, 2019	50	46
Additional paid-in capital	324,914	267,089
Accumulated other comprehensive income	73	18
Accumulated deficit	(240,596)	(164,125)
Total stockholders' equity	84,441	103,028
Total liabilities and stockholders' equity	$ 169,377	$ 174,202