

**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 12, 2020

Molecular Templates, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-32979
(Commission File Number)

94-3409596
(I.R.S. Employer Identification Number)

9301 Amberglen Blvd, Suite 100, Austin, TX 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.

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

Item 2.02. Results of Operations and Financial Condition.

On March 12, 2020, Molecular Templates, Inc. (the “Company”) announced its financial results for the fourth quarter of 2019 ended December 31, 2019. 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 March 12, 2020](#)

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: March 12, 2020

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

Molecular Templates, Inc. Reports Fourth Quarter 2019 Financial Results

AUSTIN, Texas, March 12, 2020 (GLOBE NEWSWIRE) -- Molecular Templates, Inc. (Nasdaq: MTEM, “Molecular Templates,” or “MTEM”), a clinical-stage biopharmaceutical company focused on the discovery and development of the Company’s proprietary targeted biologic therapeutics, engineered toxin bodies (ETBs), today reported financial results for the fourth quarter of 2019. As of December 31, 2019, MTEM’s cash and investments totaled \$126.6 million, which is expected to fund operations into 2022.

“In 2019, we made important progress by advancing our pipeline programs, establishing a new collaboration outside of oncology with a premier partner, and strengthening our balance sheet with a successful equity financing,” said Eric Poma, Ph.D., Molecular Templates’ Chief Executive and Scientific Officer. “We now have five ongoing studies across three clinical programs: three Phase 2 studies for MT-3724, a Phase 1 study for MT-5111, and a Phase 1 study with our partner Takeda for TAK-169. We also expect our earlier stage programs to advance in 2020, including an IND filing for MT-6402 (our PD-L1 ETB with antigen seeding), preclinical data presentations on ETBs against new targets, and continued progress in our multi-target collaborations with Takeda and Vertex.”

Company Highlights and Upcoming Milestones

Corporate

- On November 18, 2019, MTEM and Vertex Pharmaceuticals announced a strategic research collaboration to discover and develop novel targeted conditioning regimens that may enhance the hematopoietic stem cell transplant process, including transplants conducted as part of treatment with ex vivo CRISPR/Cas9 gene editing therapies such as CTX001. Under the collaboration, MTEM will conduct research activities for the use of ETBs for up to two targets selected by Vertex. The initial research will be focused on discovering a novel conditioning regimen using MTEM's ETB technology platform. In addition, Vertex has an option to select a second target as part of the collaboration. Vertex made an up-front payment of \$38 million to MTEM, including an equity investment. MTEM is also eligible to receive future development, regulatory and sales milestones and option payments of up to \$522 million (across two targets) and tiered royalty payments on future sales.
- On November 21, 2019, MTEM announced the pricing of an underwritten equity offering, the net proceeds of which were approximately \$53.4 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by MTEM.
- On February 19, 2020, MTEM announced the initiation of dosing in a Phase 1 study investigating TAK-169 in patients with relapsed/refractory multiple myeloma. Co-developed with Takeda Pharmaceutical Company Limited (“Takeda”), TAK-169 is a potential first-in-class CD38-targeting ETB. As a result of achieving this milestone, MTEM received a \$10 million payment from Takeda.

MT-3724 (CD20 ETB)

- At the American Society of Hematology (ASH) annual meeting in December 2019, MTEM presented the final results from the MT-3724 Phase 1/1b monotherapy study. The presentation included safety data on doses from 5-100 µg/kg, and efficacy data on 13 serum rituximab negative (RTX-neg) diffuse large B-cell lymphoma (DLBCL) or mixed DLBCL/FL subjects of whom 5 responded (38% objective response rate) across the range of 5 to 50 µg/kg doses. Of the 5 responses, 2 were complete responses (CRs) and 3 were partial responses (PRs). Three patients had stable disease (including 2 patients with 49% and 47% tumor reductions) and 5 patients had progressive disease. Of the 5 serum RTX-neg subjects with DLBCL who received MT-3724 at 50 µg/kg, the maximum tolerated dose (MTD), 3 responded (2 CRs, 1 PR).
- MTEM is currently conducting three ongoing Phase 2 studies in relapsed/refractory DLBCL: a monotherapy study that has the potential to be pivotal, a combination study with chemotherapy, and a combination study with lenalidomide.
- In January 2020, MTEM reported that the combination study with lenalidomide has demonstrated preliminary evidence of tolerability and efficacy with lenalidomide at standard doses and MT-3724 at 10 µg/kg. MT-3724 dosing at higher doses with lenalidomide is ongoing.
- In January 2020, MTEM reported that the combination study with GemOx has demonstrated preliminary evidence of efficacy but Grade 2 innate immune adverse effects were seen with standard doses of gemcitabine and oxaliplatin and 10 µg/kg doses of MT-3724. The study protocol has been amended to include a revised schedule in which MT-3724 dosing is initially sequenced with GemOx dosing.
- MTEM expects to report updates on all three MT-3724 studies throughout 2020.

TAK-169 (CD38 ETB)

- Takeda and MTEM are currently conducting a Phase 1 study for TAK-169 in relapsed/refractory multiple myeloma.
- In December 2019, TAK-169 received Orphan Drug Designation from the FDA.

MT-5111 (HER2 ETB)

- In December 2019, MTEM presented preclinical data on MT-5111 at the San Antonio Breast Cancer Symposium (SABCS).
- The Phase 1 study of MT-5111 in HER2-positive cancers is ongoing with multiple sites open for enrollment.
- MTEM expects to announce interim clinical results from the MT-5111 Phase 1 study in 2Q20 and additional data from the dose escalation portion of the study in 4Q20.

Research

- MTEM expects to file an IND application for MT-6402, its ETB targeting PD-L1 (with antigen seeding), in 2H20.
- Several other ETB candidates are in preclinical development against targets including CTLA-4, SLAMF-7, and CD45.

- In 2020, MTEM expects to present preclinical data on new targets and new ETBs at conferences.

Financial Results

The net loss attributable to common shareholders for the fourth quarter of 2019 was \$15.9 million, or \$0.41 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$6.6 million, or \$0.18 per basic and diluted share, for the same period in 2018.

Revenues for the fourth quarter of 2019 were \$6.2 million, compared to \$4.7 million for the same period in 2018. Revenues for the fourth quarter of 2019 were comprised of revenues from collaborative research and development agreements with Takeda, and grant revenue from CPRIT. Total research and development expenses for the fourth quarter of 2019 were \$16.6 million, compared with \$7.6 million for the same period in 2018. Total general and administrative expenses for the fourth quarter of 2019 were \$6.0 million, compared with \$3.9 million for the same period in 2018.

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 development of the MT-3724, MT-5111, TAK-169, and MT-6402; the expected timing of submitting various IND applications and conducting studies; 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 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; 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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Research and development revenue - from related party	\$ 4,688	\$ 4,077	\$ 19,499	\$ 7,087
Research and development revenue - other	—	—	—	196
Grant revenue	1,509	607	2,771	6,002
Total revenue	6,197	4,684	22,270	13,285
Operating expenses:				
Research and development	16,573	7,562	50,519	30,202
General and administrative	6,028	3,917	20,077	14,082
Loss on impairment of in-process research and development	—	—	22,123	—
Total operating expenses	22,601	11,479	92,719	44,284
Loss from operations	16,404	6,795	70,449	30,999
Interest and other income, net	873	444	2,323	751

Interest and other expense, net	(351)	(318)	(1,298)	(990)
Change in fair value of warrant liabilities	—	35	3	951
Net loss attributable to common shareholders	<u>\$ 15,882</u>	<u>\$ 6,634</u>	<u>\$ 69,421</u>	<u>\$ 30,287</u>
Net loss per share attributable to common shareholders:				
Basic and diluted	\$ 0.41	\$ 0.18	\$ 1.86	\$ 1.02
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	40,552,083	36,589,988	37,770,378	29,601,692

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

	<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 85,451	\$ 87,721
Marketable securities, current	39,633	10,234
Prepaid expenses	2,318	2,244
Grant revenue receivable	7,100	4,329
Accounts receivable from related party	408	240
In-process research and development - held for sale	4,500	—
Other current assets	489	95
Total current assets	<u>139,899</u>	<u>104,863</u>
Marketable securities, non-current	1,510	—
Operating lease right-of-use assets, non-current	9,959	—
Property and equipment, net	18,158	6,851
In-process research and development	—	26,623
Other assets	4,676	1,821
Total assets	<u>\$ 174,202</u>	<u>\$ 140,158</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,465	\$ 780
Accrued liabilities	14,544	5,357
Deferred revenue, current	17,291	26,231
Other current liabilities	2,501	141
Total current liabilities	<u>35,801</u>	<u>32,509</u>
Deferred revenue, long-term	19,385	2,670
Long-term debt, net	2,940	3,254
Operating lease liabilities, non-current	11,682	—
Other liabilities	1,366	819
Total liabilities	<u>71,174</u>	<u>39,252</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.001 par value:		
Authorized: 2,000,000 at December 31, 2019 and 2018; Issued and outstanding: 250 and zero shares at December 31, 2019 and 2018, respectively.	—	—
Common stock, \$0.001 par value:		
Authorized: 150,000,000 shares at December 31, 2019 and 2018; Issued and outstanding: 45,589,157 and 36,736,012 shares at December 31, 2019 and 2018, respectively.	46	37
Additional paid-in capital	267,089	195,573
Accumulated other comprehensive loss	18	—
Accumulated deficit	(164,125)	(94,704)
Total stockholders' equity	<u>103,028</u>	<u>100,906</u>
Total liabilities and stockholders' equity	<u>\$ 174,202</u>	<u>\$ 140,158</u>

