

**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

MOLECULAR TEMPLATES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-32979
(Commission File Number)

94-3409596
(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 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 2.02. Results of Operations and Financial Condition.

On August 12, 2021, Molecular Templates, Inc. (the "Company") announced its financial results for the second quarter of 2021 ended June 30, 2021. 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 August 12, 2021](#)

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: August 12, 2021

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

Molecular Templates, Inc. Reports Second Quarter 2021 Financial Results

AUSTIN, Texas, Aug. 12, 2021 (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), today reported financial results for the second quarter of 2021.

“We continue to make progress on advancing our wholly owned pipeline of next-generation ETBs and our existing partnerships. We reached an important milestone recently with initiation of clinical development of MT-6402 (targeting PD-L1 via dual mechanisms) which is the first of our third generation ETBs to enter the clinic,” said Eric Poma, Ph.D., Molecular Templates’ Chief Executive and Scientific Officer. “With regard to TAK-169, we are now looking forward to continuing clinical development, having assumed full rights to this asset from Takeda. We expect the second half of 2021 to be busy, with clinical data anticipated on MT-5111, TAK-169, and MT-6402 as well as further progress on our earlier stage programs.”

Company Highlights and Upcoming Milestones

Corporate

- On August 4, 2021, MTEM assumed full rights to TAK-169 from its former co-development partner, Takeda, including full control of TAK-169 clinical development.
- On April 5, 2021, MTEM announced the decision to discontinue development of MT-3724, MTEM’s only first-generation ETB. MTEM will focus on the clinical development of next-generation ETBs MT-5111, TAK-169, and MT-6402, as well as advancing next-generation preclinical ETB candidates against targets including CTLA-4, CD20, SLAMF-7, CD45, TROP2 and TIGIT.
- MTEM had three presentations at the American Association for Cancer Research (AACR) Annual Meeting 2021, which took place virtually from April 10-15, 2021:
 - MT-5111 (interim Phase 1 data as of December 2020), abstract CT130, titled “Phase 1 study of the novel immunotoxin MT-5111 in patients with HER-2+tumors.”
 - MT-6402 (preclinical data), abstract 1628, titled “Engineered toxin bodies targeting PD-L1 to alter tumor immunophenotypes and deliver broad antigenic diversity and patient coverage.”
 - CTLA-4 ETB (preclinical data), abstract 1627, titled “Preclinical characterization of a novel CTLA-4-targeted ETB for direct Treg depletion.”
- MTEM provided a corporate update and participated in 1-on-1 investor meetings at the Ladenburg Thalmann 2021 Healthcare Conference, which took place July 13-14, 2021.

MT-5111 (HER2 ETB)

- The Phase 1 study of MT-5111 in HER2-positive cancers is ongoing with multiple sites open for enrollment. Details of the study were presented at AACR in April.
- The HER2-positive breast cancer expansion cohort is planned to begin in 3Q21 at a dose of 10 mcg/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.
- Additional data from both the dose escalation portion of the study and the metastatic breast cancer dose expansion cohort are expected in 4Q21.

TAK-169 (CD38 ETB)

- On August 4, 2021, MTEM assumed full rights to TAK-169 from its former co-development partner, Takeda, including full control of TAK-169 clinical development, per the terms of the terminated collaboration agreement with Takeda. MTEM will continue conducting the ongoing Phase 1 study for TAK-169 in relapsed/refractory multiple myeloma. This study, which started dosing in February 2020, 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 re-initiated in 4Q20.
- As previously disclosed, Takeda had enrolled and treated four subjects in the Phase 1 study. Pharmacodynamic activity was noted in the subjects, all treated at the starting dose of 50 mcg/kg. Clearance of natural killer (NK) cells in peripheral blood was observed in all subjects with a maximal reduction of peripheral NK cells of 56%, 85%, 88%, and 92%, respectively, after the first dose. The subject with 56% reduction in NK cells exhibited a low percentage of CD38+ NK cells. These values appear comparable to the reported maximal peripheral NK clearance seen with CD38-targeting antibodies at receptor-saturating doses. The geometric mean of C_{max} in these four subjects appears lower than the predicted EC₅₀ observed in patient-derived ex vivo cell-kill assays but above in vitro EC₅₀ values in multiple myeloma cell-lines.
- MTEM expects to provide an update on the Phase 1 study in 4Q21.

MT-6402 (PD-L1 ETB with antigen seeding)

- In July 2021, MTEM dosed its first subject in a Phase 1 study of MT-6402. MT-6402 is the first of MTEM’s 3rd generation ETBs to enter the clinic. MT-6402 was designed to induce potent anti-tumor effects via PD-L1 targeting through multiple mechanisms that may overcome the limitations of the PD-L1 antibodies.
- The Phase 1 study is a multi-center, open-label, dose escalation and dose expansion trial in 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. The

starting dose is 16 mcg/kg.

- Following determination of the maximum tolerated dose (MTD) or recommended Phase 2 dose, expansion cohorts are planned to evaluate MT-6402 as a monotherapy in tumor-specific and tumor-agnostic cohorts.
- MTEM expects to provide an update on the Phase 1 study in 4Q21.

Research

- MTEM expects to initiate a Phase 1 study for an ETB targeting CTLA-4 in 2022.
- Several other wholly owned ETB candidates are in preclinical development against targets including CD20, SLAMF-7, CD45, TROP2, and TIGIT.
- In 2021, MTEM expects to present preclinical data on ETB candidates at medical and scientific conferences.

Financial Results

The net loss attributable to common shareholders for the second quarter of 2021 was \$15.6 million, or \$0.28 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$31.2 million, or \$0.68 per basic and diluted share, for the same period in 2020.

Revenues for the second quarter of 2021 were \$15.1 million, compared to \$6.9 million for the same period in 2020. Revenues for the second quarter of 2021 were comprised of revenues from collaborative research and development agreements with Takeda, Vertex and Bristol Myers Squibb. Total research and development expenses for the second quarter of 2021 were \$21.1 million, compared with \$30.4 million for the same period in 2020. Total general and administrative expenses for the second quarter of 2021 were \$8.9 million, compared with \$6.4 million for the same period in 2020.

As of June 30, 2021, MTEM's cash and investments totaled \$200.7 million. MTEM's current cash and investments are expected to fund operations into the second half of 2023.

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 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 regarding the safety or potential efficacy of Molecular Templates' drug or biologic candidates, including the anticipated benefits of Molecular Templates' next-generation ETBs compared to its first-generation ETBs, such as MT-3724; statements relating to the development of MT-5111, TAK-169, and MT-6402; the expected timing of submitting various IND applications and conducting studies and generating data; Molecular Templates' receipt of future development, regulatory and sales milestones and royalty payments; the expected participation and presentation at upcoming conferences; the anticipated effects of the COVID-19 pandemic on Molecular Templates' ongoing clinical studies, manufacturing and preclinical development; and Molecular Templates' 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 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; 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 Molecular Templates' filings with the SEC. 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.

Contacts:

Sean McLennan
Interim Chief Financial Officer
sean.mclennan@mtmem.com
512-334-6664

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

| | Three Months Ended | | Six Months Ended | |
|--|---------------------------|------------------|-------------------------|------------------|
| | March 31, | | June 30, | |
| | 2021 | 2020 | 2021 | 2020 |
| Research and development revenue, related party | \$ 12,899 | \$ 3,063 | \$ 13,136 | \$ 3,396 |
| Research and development revenue, other | 2,235 | 2,977 | 5,218 | 4,444 |
| Grant revenue | — | 869 | — | 3,210 |
| Total revenue | <u>15,134</u> | <u>6,909</u> | <u>18,354</u> | <u>11,050</u> |
| Operating expenses: | | | | |
| Research and development | 21,127 | 30,414 | 42,447 | 51,045 |
| General and administrative | 8,922 | 6,412 | 17,151 | 12,059 |
| Total operating expenses | <u>30,049</u> | <u>36,826</u> | <u>59,598</u> | <u>63,104</u> |
| Loss from operations | 14,915 | 29,917 | 41,244 | 52,054 |
| Interest and other income, net | 81 | 286 | 133 | 758 |
| Interest and other expense, net | (767) | (360) | (1,268) | (708) |
| Loss on extinguishment of debt | — | (1,237) | — | (1,237) |
| Loss before provision for income taxes | 15,601 | 31,228 | 42,379 | 53,241 |
| Provision for income taxes | — | — | — | 5 |
| Net loss | <u>15,601</u> | <u>31,228</u> | <u>42,379</u> | <u>53,246</u> |
| Net loss attributable to common shareholders | <u>\$ 15,601</u> | <u>\$ 31,228</u> | <u>\$ 42,379</u> | <u>\$ 53,246</u> |
| Net loss per share attributable to common shareholders: | | | | |
| Basic and diluted | \$ 0.28 | \$ 0.68 | \$ 0.78 | \$ 1.17 |
| Weighted average number of shares used in net loss per share calculations: | | | | |
| Basic and diluted | 56,096,238 | 45,725,481 | 54,340,173 | 45,687,278 |

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

| | June 30, | December 31, |
|---|------------------------|---------------------|
| | 2021(unaudited) | 2020 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 43,090 | \$ 25,218 |
| Marketable securities, current | 154,512 | 68,667 |
| Prepaid expenses | 7,212 | 6,080 |
| Accounts receivable, related party | — | 234 |
| Other current assets | 465 | 1,125 |
| Total current assets | <u>205,279</u> | <u>101,324</u> |
| Marketable securities, non-current | 3,072 | — |
| Operating lease right-of-use assets | 10,138 | 11,104 |
| Property and equipment, net | 21,206 | 22,254 |
| Other assets | 5,066 | 5,195 |
| Total assets | <u>\$ 244,761</u> | <u>\$ 139,877</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,907 | \$ 2,350 |
| Accrued liabilities | 9,074 | 12,575 |

| | | |
|--|------------|------------|
| Deferred revenue, current | 30,791 | 14,014 |
| Deferred revenue, current, related party | — | 789 |
| Other current liabilities, related party | 472 | 5,614 |
| Other current liabilities | 2,464 | 2,211 |
| Total current liabilities | 44,708 | 37,553 |
| Deferred revenue, long-term | 52,544 | 4,538 |
| Deferred revenue, long-term, related party | 2,586 | 3,106 |
| Long-term debt, net of current portion | 35,018 | 14,926 |
| Operating lease liabilities | 10,947 | 12,213 |
| Other liabilities, related party | — | 6,711 |
| Other liabilities | 1,556 | 1,490 |
| Total liabilities | 147,359 | 80,537 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity | | |
| Preferred stock, \$0.001 par value: | | |
| Authorized: 2,000,000 shares at June 30, 2021 and December 31, 2020; issued and outstanding: 250 shares at June 30, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.001 par value: | | |
| Authorized: 150,000,000 shares at June 30, 2021 and December 31, 2020; issued and outstanding: 56,138,404 shares at June 30, 2021 and 49,984,333 shares at December 31, 2020 | 56 | 50 |
| Additional paid-in capital | 408,758 | 328,314 |
| Accumulated other comprehensive income | 8 | 17 |
| Accumulated deficit | (311,420) | (269,041) |
| Total stockholders' equity | 97,402 | 59,340 |
| Total liabilities and stockholders' equity | \$ 244,761 | \$ 139,877 |