August 12, 2021

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 Cmax 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.

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

	Three Months Ended March 31,		Six Months Ended 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	15,134	6,909	18,354	11,050
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	30,049	36,826	59,598	63,104
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	15,601	31,228	42,379	53,246
Net loss attributable to common shareholders	$ 15,601	$ 31,228	$ 42,379	$ 53,246
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, 2021 (unaudited)	December 31, 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	205,279	101,324
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	$ 244,761	$ 139,877
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

Source: Molecular Templates, Inc.