August 6, 2020

Molecular Templates, Inc. Reports Second Quarter 2020 Financial Results

AUSTIN, Texas, Aug. 06, 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 second quarter of 2020.

"Since our last quarterly update, we presented preclinical data at AACR on four preclinical ETB programs, provided an update on the ongoing Phase I study for MT-5111, and strengthened our balance sheet through a new debt facility and our ATM," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Chief Scientific Officer. "In the second half of 2020, we expect to report interim clinical data from our three MT-3724 Phase 2 studies and additional data from the MT-5111 Phase 1 study, and also file the IND for MT-6402, our PD-L1-targeted ETB with antigen seeding."

Company Highlights, Pipeline Status, and Upcoming Milestones

Corporate

- On May 22, 2020, MTEM announced it had secured a debt financing facility for up to $45 million from K2 HealthVentures, a healthcare-focused specialty finance company. MTEM received a first tranche of $15 million upon closing. Two subsequent tranches totaling $30 million will become available upon the achievement of certain milestones.
- In July 2020, MTEM raised $50 million in gross proceeds from its At-The-Market Facility (ATM).

MT-3724 (CD20 ETB)

- MTEM is currently conducting three Phase 2 studies with MT-3724 in relapsed/refractory diffuse large B-cell lymphoma (DLBCL): a monotherapy study that has the potential to be pivotal, a combination study with chemotherapy, and a combination study with lenalidomide.
- Interim results for the study of MT-3724 in combination with lenalidomide were presented at the 25th Congress of the European Hematology Association (EHA) virtual meeting in June 2020. This data demonstrated preliminary evidence of tolerability and efficacy with lenalidomide at standard doses and MT-3724. Among 7 evaluable subjects, 2 had CRs and 3 had PRs. While there were no permanent discontinuations due to adverse events, grade 2 capillary leak syndrome occurred at 25 mcg/kg, leading to the opening of a new cohort at 20 mcg/kg. The study now has a new schedule of therapy with MT-3724 being dosed twice rather than three times weekly for the first two cycles, and then on a weekly schedule thereafter.

- MTEM expects to report updates on all three MT-3724 DLBCL studies in 2H20.
- MTEM also expects to initiate Phase 2 studies for MT-3724 in follicular lymphoma and mantle cell lymphoma in 2H20.

TAK-169 (CD38 ETB)

- Takeda and MTEM are conducting an ongoing Phase 1 study evaluating TAK-169 in relapsed/refractory multiple myeloma.

MT-5111 (HER2 ETB)

- MTEM is conducting a Phase 1 study of MT-5111 in HER2-positive cancers.
- In June 2020, MTEM provided an interim update from the first three dose cohorts of the dose escalation portion of the Phase 1 study. That update noted that 10 subjects, with a median of 5 prior lines of therapy and a median of 2 prior HER2-targeting regimens, have been treated with MT-5111 (metastatic cholangiocarcinoma n=5, metastatic breast cancer n=4, metastatic gastro-esophageal junction carcinoma n=1). Thus far, no dose limiting toxicities (DLTs) have been observed in any cohort and MT-5111 appears to be well tolerated, with no cardiotoxicity observed to date (cardiotoxicity is a known potential toxicity for HER2 targeted therapies).
- Further to the June 2020 interim update, MTEM expects to provide an update on results from the subjects still on treatment as well as higher dose cohorts from the dose escalation portion of the Phase 1 study (including doses that are predicted to be clinically active based on preclinical data) in 4Q20.

Research

- MTEM presented preclinical data on ETB programs targeting PD-L1, CTLA-4, SLAMF-7 and CD45 at the American Association for Cancer Research (AACR) Virtual Annual Meeting II, which took place June 22-24, 2020.
- MTEM expects to file an investigational new drug (IND) application for MT-6402, its ETB targeting PD-L1 (with antigen seeding), in 2H20.
- 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. Much like 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 slower pace than was projected pre-COVID-19.
- To date, MTEM has been able to continue to work at 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.

Financial Results

The net loss attributable to common shareholders for the second quarter of 2020 was $31.2 million, or $0.68 per basic and diluted share. This compares with a net loss attributable to common shareholders of $9.2 million, or $0.25 per basic and diluted share, for the same period in 2019.

Revenues for the second quarter of 2020 were $6.9 million, compared to $5.4 million for the same period in 2019. Revenues for the second quarter of 2020 were comprised of revenues from collaborative research and development agreements with Takeda and Vertex, as well as grant revenue from CPRIT. Total research and development expenses for the second quarter of 2020 were $30.4 million, compared with $10.2 million for the same period in 2019. Total general and administrative expenses for the second quarter of 2020 were $6.4 million, compared with $4.6 million for the same period in 2019.

As of June 30, 2020, MTEM's cash and investments totaled $91.0 million. With the addition of $50 million in gross proceeds raised through MTEM's ATM facility after the end of the quarter, MTEM expects to be able 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 development of the MT-3724, MT-5111, TAK-169, and MT-6402; 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 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development revenue, related party	$ 3,063	$ 5,211	$ 3,396	$ 11,624
Research and development revenue, other	2,977	—	4,444	—
Grant revenue	869	236	3,210	831
Total revenue	6,909	5,447	11,050	12,455
Operating expenses:				
Research and development	30,414	10,243	51,045	18,697
General and administrative	6,412	4,605	12,059	9,540
Total operating expenses	36,826	14,848	63,104	28,237
Loss from operations	29,917	9,401	52,054	15,782
Interest and other income, net	286	543	758	1,053
Interest and other expense, net	(360)	(301)	(708)	(594)
Loss on extinguishment of debt	(1,237)	—	(1,237)	—
Change in fair value of warrant liabilities	—	6	—	2
Loss before provision for income taxes	31,228	9,153	53,241	15,321
Provision for income taxes	—	—	5	—
Net loss	31,228	9,153	53,246	15,321
Net loss attributable to common shareholders	$ 31,228	$ 9,153	$ 53,246	$ 15,321
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 0.68	$ 0.25	$ 1.17	$ 0.42
Weighted average number of shares used in net loss per share calculations:	45,725,481	36,819,846	45,687,278	36,779,638
Basic and diluted				

Molecular Templates, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,645	$ 85,451
Marketable securities, current	63,361	39,633
Prepaid expenses	3,347	2,318
Grants revenue receivable	5,900	7,100
Accounts receivable, related party	3,167	408
In-process research and development - held for sale	4,500	4,500
Other current assets	160	489
Total current assets	108,080	139,899
Marketable securities, non-current	—	1,510
Operating lease right-of-use assets, non-current	9,266	9,959
Property and equipment, net	20,224	18,158
Other assets	4,840	4,676
Total assets	$ 142,410	$ 174,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,660	$ 1,465
Accrued liabilities	14,129	14,544
Deferred revenue, current	13,284	8,511
Deferred revenue, current, related party	5,218	8,780
Other current liabilities, related party	5,325	—
Other current liabilities	1,785	2,501
Total current liabilities	41,401	35,801
Deferred revenue, long-term	9,728	18,944
Deferred revenue, long-term, related party	1,849	441
Long-term debt, net	14,721	2,940
Operating lease liabilities, non-current	10,771	11,682
Other liabilities, related party	6,654	—
Other liabilities	1,427	1,366
Total liabilities	86,551	71,174
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at June 30, 2020 and December 31, 2019; issued and outstanding: 250 shares at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares; issued and outstanding: 45,778,876 shares at June 30, 2020 and 45,589,157 shares at December 31, 2019	46	46
Additional paid-in capital	273,012	267,089
Accumulated other comprehensive income	172	18
Accumulated deficit	(217,371)	(164,125)
Total stockholders' equity	55,859	103,028
Total liabilities and stockholders' equity	$ 142,410	$ 174,202

Source: Molecular Templates, Inc.