

Molecular Templates, Inc. Reports Third Quarter 2021 Financial Results

AUSTIN, Texas, Nov. 15, 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 third quarter of 2021.

"We are focused on execution across our growing portfolio of wholly owned next-generation ETBs," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Scientific Officer. "Third quarter highlights included the initiation of clinical development of MT-6402 (targeting PD-L1 via dual mechanisms), the initiation of the HER2-positive breast cancer expansion cohort for MT-5111 as well as continued enrollment of patients in our MT-0169 clinical program. These programs demonstrate the depth and versatility of our ETB platform and the potential to develop innovative treatments for a broad array of solid and hematological tumors with high unmet medical need."

Company Highlights and Upcoming Milestones

Corporate

- 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 incorporating Antigen Seeding Technology to enter the clinic and represents a new approach to immuno-oncology.
- On August 4, 2021, MTEM assumed full rights to TAK-169, now known as MT-0169, from its former co-development partner, Takeda, including full control of MT-0169 clinical development.
- Enrollment in the MT-0169 Phase 1 study in relapsed/refractory multiple myeloma has resumed after the transfer of the IND to MTEM.
- MTEM expects to provide an update on MT-5111, MT-0169 and MT-6402 by the end
 of this year and expects to provide periodic updates throughout 2022.

MT-0169 (CD38 ETB)

- On August 4, 2021, MTEM assumed full rights to MT-0169 from its former codevelopment partner, Takeda, including full control of MT-0169 clinical development, per the terms of the terminated collaboration agreement with Takeda. MTEM will continue conducting the ongoing Phase 1 study for MT-0169 in relapsed/refractory multiple myeloma and non-Hodgkin's lymphoma.
- Patient enrollment in the 50 mcg/kg cohort is currently ongoing. MTEM continues to see pharmacodynamic activity with MT-0169. Data on the first four patients treated in the Phase 1 study evaluating MT-0169 was presented in a poster at the Society for Immunotherapy of Cancer (SITC) annual meeting on November 12.

MT-6402 (PD-L1 ETB with Antigen Seeding Technology)

- MTEM is enrolling patients in the Phase 1 study of MT-6402 which initiated in July 2021. MT-6402 is the first of MTEM's 3rd generation ETBs to enter the clinic. It was designed to induce potent anti-tumor effects via PD-L1 targeting through multiple mechanisms that may overcome the limitations of PD-L1 antibody therapies.
- 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 are eligible for enrollment.
- Patient enrollment in the 16 mcg/kg cohort (the starting dose) is currently ongoing.
 There have been no dose limiting toxicities and no signs of capillary leak syndrome observed to date.
- 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.

MT-5111 (HER2 ETB)

- The Phase 1 study of MT-5111 in HER2-positive cancers is ongoing with multiple sites open for enrollment.
- The HER2-positive breast cancer expansion cohort initiated as of November 2021 at a
 dose of 10 mcg/kg (anticipated to be a therapeutic dose level). Dose escalation will
 continue to determine the recommended Phase 2 dose while the breast cancer
 expansion cohort collects efficacy and safety data.

Research

- MTEM continues to advance its pipeline of next-generation ETBs targeting CTLA-4, TIGIT, TROP2, SLAMF-7, CD20, and CD45.
- A poster on ETB mediated depletion of TIGIT expressing immune cells for cancer immunotherapy was presented at the SITC annual meeting on November 13
- Through 2021 and in 2022, MTEM expects to present preclinical data on ETB candidates at medical and scientific conferences.

Upcoming Investor Events

- Stifel Healthcare Conference (November 15-17, 2021)
- Evercore ISI 4th Annual HealthCONx (November 30 December 2, 2021)

Financial Results

The net loss attributable to common shareholders for the third quarter of 2021 was \$30.4 million, or \$0.54 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$23.2 million, or \$0.47 per basic and diluted share, for the same period in 2020.

Revenues for the third quarter of 2021 were \$2.4 million, compared to \$4.3 million for the same period in 2020. Revenues for the third quarter of 2021 were comprised of revenues from collaborative research and development agreements with Vertex and Bristol Myers

Squibb. Total research and development expenses for the third quarter of 2021 were \$22.9 million, compared with \$19.6 million for the same period in 2020. Total general and administrative expenses for the third quarter of 2021 were \$9.0 million, compared with \$7.5 million for the same period in 2020.

As of September 30, 2021, MTEM's cash and investments totaled \$175.4 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; statements relating to the development of MT-5111, MT-0169, 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 September 30,			Nine Months Ended September 30,				
		2021		2020		2021		2020
Research and development revenue, related party	\$	_	\$	1,566	\$	13,136	\$	4,962
Research and development revenue, other		2,379		2,732		7,597		7,176
Grant revenue		_		_		_		3,210
Total revenue		2,379		4,298		20,733		15,348
Operating expenses:								
Research and development		22,881		19,622		65,328		70,667
General and administrative		9,027		7,547		26,178		19,606
Total operating expenses		31,908		27,169		91,506		90,273
Loss from operations		29,529		22,871		70,773		74,925
Interest and other income, net		175		167		308		925
Interest and other expense, net		(1,033)		(521)		(2,301)		(1,229)
Loss on extinguishment of debt				_				(1,237)
Loss before provision for income taxes		30,387		23,225		72,766		76,466
Provision for income taxes				_				5
Net loss		30,387		23,225		72,766		76,471
Net loss attributable to common shareholders	\$	30,387	\$	23,225	\$	72,766	\$	76,471
Net loss per share attributable to common shareholders:								
Basic and diluted	\$	0.54	\$	0.47	\$	1.32	\$	1.63
Weighted average number of shares used in net loss per								
share calculations:								
Basic and diluted		56,174,644		49,026,499		54,958,365		46,808,437
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Molecular Templates, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2021(unaudited)			December 31, 2020	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	27,593	\$	25,218	
Marketable securities, current		141,783		68,667	
Prepaid expenses		7,623		6,080	
Accounts receivable, related party		_		234	
Other current assets		445		1,125	
Total current assets		177,444		101,324	
Marketable securities, non-current		6,013		_	
Operating lease right-of-use assets		9,002		11,104	
Property and equipment, net		20,451		22,254	
Other assets		5,019		5,195	
Total assets	\$	217,929	\$	139,877	
LIABILITIES AND STOCKHOLDERS' EQUITY	===				
Current liabilities:					
Accounts payable	\$	1,311	\$	2,350	
Accrued liabilities	Ψ	11,305	Ψ	12,575	
Deferred revenue, current		32,240		14,014	
Deferred revenue, current, related party		02,240		789	
Other current liabilities, related party		_		5,614	
Other current liabilities		2,541		2,211	
Total current liabilities		47,397		37,553	
Deferred revenue, long-term		51,302		4,538	
Deferred revenue, long-term, related party		31,302		3,106	
Long-term debt, net of current portion		35,251		14,926	
Operating lease liabilities		10,284		12,213	
Other liabilities, related party		10,204		6,711	
Other liabilities		1,590		1,490	
Total liabilities		145,824		80,537	
Commitments and contingencies (Note 10)		143,024		00,337	
Stockholders' equity					
Preferred stock, \$0.001 par value:					
Authorized: 2,000,000 shares at September 30, 2021 and					
December 31, 2020; issued and outstanding: 250 shares at September 30, 2021 and December 31, 2020		_		_	
Common stock, \$0.001 par value:					
Authorized: 150,000,000 shares at September 30, 2021 and					
December 31, 2020; issued and outstanding: 56,297,967 shares at		=0			
September 30, 2021 and 49,984,333 shares at December 31, 2020		56		50	
Additional paid-in capital		413,857		328,314	
Accumulated other comprehensive income, (loss)		(1)		(000,044)	
Accumulated deficit		(341,807)		(269,041)	
Total stockholders' equity		72,105		59,340	
Total liabilities and stockholders' equity	\$	217,929	\$	139,877	



Source: Molecular Templates, Inc.