

Molecular Templates, Inc. Reports Fourth Quarter 2021 Financial Results

AUSTIN, Texas, March 28, 2022 (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 fourth quarter of 2021.

"2022 is off to a very promising start, following a number of important developments across our pipeline of ETBs in 2021," said Eric Poma, Ph.D., Chief Executive and Chief Scientific Officer of Molecular Templates. "We continue to see differentiated pharmacodynamic effects and evidence of antigen seeding with MT-6402 with additional data expected throughout 2022. We continue dose finding for the MT-5111 and MT-0169 programs with clinical data expected this year. We plan to file an IND in 2H22 for our CTLA-4 program and are moving forward with our earlier stage pipeline of ETBs in preclinical development targeting TIGIT, TROP-2, and BCMA."

Company Highlights and Upcoming Milestones

Corporate

- MTEM expects to provide periodic updates on MT-6402, MT-5111, and MT-0169 throughout 2022.
- MTEM has had six abstracts accepted for presentation at the upcoming American Association for Cancer Research (AACR) Meeting 2022, taking place from April 8-13, 2022.
- Gabriela Gruia, M.D. appointed to the Board of Directors.
- Megan Filoon promoted to General Counsel.

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

- MTEM continues to enroll patients in the Phase 1 study of MT-6402 which began 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 approved checkpoint inhibitors.
- 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.
- The 16 mcg/kg cohort (cohort 1) was completed with no DLTs observed in the six patients treated. One patient in cohort 1 with non-small cell lung cancer (NSCLC) had evaluable-only multiple sites of bone disease that appeared to have resolved on bone scan with only one remaining site which showed decreased uptake. This patient

- remained on MT-6402 up to cycle 8 when increased uptake was noted on bone scan and treatment was discontinued.
- Six patients have been treated in the 24 mcg/kg cohort (cohort 2). One DLT, a grade 3 dermatitis of two days duration, occurred six days after the first dose in cohort 2 in one patient. The patient was treated with systemic steroids and treatment with MT-6402 was held until cycle 2, dose 1, at which time the patient was re-challenged at the same dose without development of recurrent dermatitis.
- Following a review of the safety data from cohort 2 (24 mcg/kg), patient enrollment in cohort 3 initiated at a dose of 32 mcg/kg.
- MTEM continues to observe pharmacodynamic (PD) effects including monocyte depletion and T cell activation in the 24 mcg/kg cohort. The extent and timing of these PD effects appear dose-related with patients in the 24 mcg/kg generally showing a more rapid and profound PD effect.
- Six patients remain on study with five patients awaiting their first efficacy assessment.
 Dose escalation continues as planned and following determination of the maximum tolerated dose (MTD), expansion cohorts are planned to evaluate MT-6402 as a monotherapy in tumor-specific and PD-L1 positive basket tumor cohorts.
- In 2021, MT-6402 was granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of patients with advanced NSCLC expressing PD-L1.

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 in November 2021 at a dose of 10 mcg/kg.
- As of January 2022, 30 patients had been treated with MT-5111 across eight dose escalation cohorts ranging from 0.5 mcg/kg to 13 mcg/kg without any DLTs.
- There have been no signs of capillary leak syndrome (CLS) or significant cardiotoxicity observed to date with MT-5111.
- Enrollment has initiated for the next cohort at 17 mcg/kg. Dose escalation will continue to determine the MTD, while the breast cancer expansion cohort collects efficacy and safety data.

MT-0169 (CD38 ETB)

- In August 2021, MTEM assumed full rights to MT-0169 from its former co-development partner, Takeda, including full control of MT-0169 clinical development, per the terms of the terminated collaboration agreement with Takeda. Upon approval of a revised protocol, MTEM will continue to conduct the ongoing Phase 1 study for MT-0169 in relapsed/refractory multiple myeloma and non-Hodgkin's lymphoma and plans to open new sites for the Phase I study.
- A more rapid and complete elimination of CD38+ NK cells (a known PD marker for CD38-targeting therapeutics) was observed in the first five patients than had been predicted from in vitro and in vivo models, suggesting that the starting dose of 50 mcg/kg is higher than required.
- A revised protocol was submitted to explore a lower dose of MT-0169 to reduce the risk of adverse events observed at the initial dose and to enable patients to continue

MT-0169 therapy for a longer duration that may drive tumor benefit. Importantly, the robust and rapid NK cell depletion that was observed at the starting dose is expected to be observed at lower doses.

Research

- MTEM continues to advance its pipeline of next-generation ETBs targeting CTLA-4, TIGIT, TROP2, BCMA, SLAMF-7, and CD45.
- IND filing of an ETB in the CTLA-4 program is expected in 2H22.
- Lead selection for TIGIT, TROP-2, and BCMA is ongoing.
- MTEM plans to present preclinical data on its ETB candidates at AACR in April 2022 and expects to present further preclinical data throughout the year at medical and scientific conferences.

Financial Results for the Fourth Quarter of 2021

The net loss attributable to common shareholders for the fourth quarter of 2021 was \$10.2 million, or \$0.18 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$28.4 million, or \$0.57 per basic and diluted share, for the same period in 2020.

Revenues for the fourth quarter of 2021 were \$18.0 million, compared to \$3.5 million for the same period in 2020. Revenues for the fourth 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 fourth quarter of 2021 were \$19.3 million, compared with \$22.3 million for the same period in 2020. Total general and administrative expenses for the fourth quarter of 2021 were \$7.9 million, compared with \$7.1 million for the same period in 2020.

As of December 31, 2021, MTEM's cash and investments totaled \$152.0 million. MTEM's current cash and investments are expected to fund operations into the fourth quarter 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; statements relating to the development of MT-5111, MT-0169, and MT-6402; the expected timing for submitting various IND applications and conducting studies and generating data; the expected participation and presentation at upcoming conferences; the expected timing for providing updates on MT-6402, MT-5111, and MT-0169, including any pre-clinical data; Molecular Templates' future cash needs and the length of time for which Molecular Templates' cash resources are expected to be sufficient; 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 December 31,				Year Ended December 31,				
	 2021		2020		2021		2020		
Research and development revenue - from related party	\$ _	\$	1,605	\$	13,136	\$	6,567		
Research and development revenue - other	17,964		1,892		25,561		9,068		
Grant revenue	_		_		_		3,210		
Total revenue	17,964		3,497		38,697		18,845		
Operating expenses:									
Research and development	19,337		22,298		84,665		92,965		
General and administrative	7,928		7,116		34,106		26,722		
Total operating expenses	27,265		29,414		118,771		119,687		
Loss from operations	 9,301		25,917		80,074		100,842		
Interest and other income, net	126		103		434		1,028		
Interest and other expense, net	(1,068)		(486)		(3,369)		(1,705)		
Loss on Extinguishment of Debt	_		_		_		(1,237)		
Loss on disposal of assets	_		(2,155)		_		(2,155)		
Loss before provision (benefit) for income taxes	10,243		28,455		83,009		104,911		
Provision for income taxes	_		_				5		
Net loss attributable to common shareholders	\$ 10,243	\$	28,455	\$	83,009	\$	104,916		
Net loss per share attributable to common shareholders:	 								
Basic and diluted	\$ 0.18	\$	0.57	\$	1.50	\$	2.20		
Weighted average number of shares used in net loss per share calculations:									
Basic and diluted	56,305,049		49,970,514		55,297,798		47,603,261		

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

	Decer 2			
ASSETS			-	
Current assets:				
Cash and cash equivalents	\$	24,983	\$	25,218
Marketable securities, current		118,061		68,667
Prepaid expenses		3,917		4,140
Accounts receivable, related party		_		234
Other current assets		1,254		1,125
Total current assets		148,215		99,384
Marketable securities, non-current		8,986		_
Operating lease right-of-use assets		8,608		11,104
Property and equipment, net		19,309		22,254
Other assets		7,244		7,135
Total assets	\$	192,362	\$	139,877
LIABILITIES AND STOCKHOLDERS' EQUITY	<u> </u>			
Current liabilities:				
Accounts payable	\$	1.612	\$	2,350
Accrued liabilities	•	9,515	*	12,575
Deferred revenue, current		32,937		14,014
Deferred revenue, current, related party		´ <u>—</u>		789
Other current liabilities, related party		_		5,614
Other current liabilities		2,606		2,211
Total current liabilities		46,670		37,553
Deferred revenue, long-term		33,350		4,538
Deferred revenue, long-term, related party		_		3,106
Long-term debt, net of current portion		35,491		14,926
Operating lease liabilities		9,564		12,213
Other liabilities, related party		_		6,711
Other liabilities		1,625		1,490
Total liabilities		126,700		80,537
Commitments and contingencies (Note 10)		-		
Stockholders' equity				
Preferred stock, \$0.001 par value:				
Authorized: 2,000,000 shares at December 31, 2021 and December 31, 2020; issued and outstanding: 250 shares at				
December 31, 2021 and December 31, 2020		_		_
Common stock, \$0.001 par value: Authorized: 150,000,000 shares at December 31, 2021 and				
December 31, 2020; issued and outstanding: 56,305,049 shares at				
December 31, 2021 and 49,984,333 shares at December 31, 2020		56		50
Additional paid-in capital		417,704		328,314
Accumulated other comprehensive income, (loss)		(48)		17
Accumulated deficit		(352,050)		(269,041)
Total stockholders' equity		65,662		59,340
Total liabilities and stockholders' equity	\$	192,362	\$	139,877



Source: Molecular Templates, Inc.