

Molecular Templates, Inc. Reports First Quarter 2021 Financial Results

AUSTIN, Texas, May 13, 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 first quarter of 2021.

"We are focused on advancing our wholly owned pipeline of next-generation ETBs and our existing partnerships following the assumption of full rights to TAK-169 from Takeda and the discontinuation of the MT-3724 program," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Scientific Officer. "Over the remainder of 2021, we expect to generate clinical data from MT-5111, TAK-169, and MT-6402 and advance our earlier stage programs."

Company Highlights and Upcoming Milestones

Corporate

- On February 11, 2021, MTEM and Bristol Myers Squibb announced a strategic research collaboration to discover and develop multiple novel therapies designed for specific oncology targets. Under the collaboration, MTEM will conduct research activities for the discovery of next generation ETBs for multiple targets, of which the first target has been selected by Bristol Myers Squibb. Bristol Myers Squibb made an up-front payment of \$70 million to MTEM and MTEM is also eligible to receive nearterm and development, regulatory and sales milestone payments of up to approximately \$1.3 billion as well as tiered royalty payments on future sales.
- On February 18, 2021, MTEM announced the pricing of an underwritten public equity offering, the gross proceeds of which were approximately \$75.9 million.
- On April 5, 2021, MTEM announced that following discussion with its co-development partner Takeda, MTEM will assume full rights to TAK-169 including taking control of clinical development from Takeda. In addition, 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 and TROP2.
- 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."

MT-5111 (HER2 ETB)

- The Phase 1 study of MT-5111 in HER2-positive cancers is ongoing with multiple sites open for enrollment.
- In December 2020, MTEM provided an update on the ongoing Phase 1 study, details
 of which were presented at AACR in April. No dose limiting toxicities were observed in
 any cohort and no signs of cardiotoxicity have been observed to date, while monitoring
 the subjects' EKGs, troponin values and pro-BNP with each treatment, and serial
 echocardiograms with every other cycle. No cases of capillary leak syndrome, or CLS,
 (any grade) were observed.
- 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.
- MTEM expects to provide an update on additional data from both the dose escalation portion of the study and the metastatic breast cancer dose expansion cohort in 4Q21.

TAK-169 (CD38 ETB)

- As announced on April 5, 2021, MTEM will assume full rights to TAK-169 including taking control of clinical development from 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 earlystage studies) due to COVID-19 and was re-initiated in 4Q20.
- MTEM expects to provide an update on the Phase 1 study in 4Q21.

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

- On January 19, 2021, MTEM announced that the U.S. Food and Drug Administration (FDA) accepted its Investigational New Drug (IND) application for MT-6402.
- MTEM expects to start dosing in a first-in-human Phase 1 study in relapsed/refractory patients with PD-L1-positive solid tumors in 2Q21. The Phase 1 study is planned as a multi-center, open-label, dose escalation and dose expansion trial. Patients with confirmed PD-L1 expressing tumors or confirmed PD-L1 expression in the tumor microenvironment will be eligible to screen for enrollment in the clinical trial. Following determination of the maximum tolerated dose (MTD) or recommended Phase 2 dose, expansion cohorts are planned to study 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, and TROP2.

 In 2021, MTEM expects to present preclinical data on new targets and new ETBs at medical and scientific conferences.

Financial Results

The net loss attributable to common shareholders for the first quarter of 2021 was \$26.8 million, or \$0.51 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$22.0 million, or \$0.48 per basic and diluted share, for the same period in 2020.

Revenues for the first quarter of 2021 were \$3.2 million, compared to \$4.1 million for the same period in 2020. Revenues for the first 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 first quarter of 2021 were \$21.4 million, compared with \$20.6 million for the same period in 2020. Total general and administrative expenses for the first quarter of 2021 were \$8.2 million, compared with \$5.6 million for the same period in 2020.

As of March 31, 2021, MTEM's cash and investments totaled \$207.4 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, 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; 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.

	IVIAI	Walti Ji,		
	2021	2020		
Research and development revenue, related party	\$ 237	\$ 333		
Research and development revenue, other	2,983	1,467		
Grant revenue		2,341		
Total revenue	3,220	4,141		
Operating expenses:				
Research and development	21,368	20,631		
General and administrative	8,181	5,647		
Total operating expenses	29,549	26,278		
Loss from operations	26,329	22,137		
Interest and other income, net	52	472		
Interest and other expense, net	(501) (348)		
Loss before provision for income taxes	26,778	22,013		
Provision for income taxes		. 5		
Net loss	26,778	22,018		
Net loss attributable to common shareholders	\$ 26,778	\$ 22,018		
Net loss per share attributable to common shareholders:				
Basic and diluted	\$ 0.51	\$ 0.48		
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	52,564,628	45,649,065		

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

	March 31, 2021 (unaudited)		December 31, 2020	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	98,786	\$	25,218
Marketable securities, current		103,498		68,667
Prepaid expenses		6,178		6,080
Accounts receivable, related party		_		234
Other current assets		719		1,125
Total current assets		209,181		101,324
Marketable securities, non-current		5,115		· —
Operating lease right-of-use assets		10,625		11,104
Property and equipment, net		21,707		22,254
Other assets		5,146		5,195
Total assets	\$	251,774	\$	139,877
LIABILITIES AND STOCKHOLDERS' EQUITY		_		
Current liabilities:				
Accounts payable	\$	1,804	\$	2,350
Accrued liabilities		9,801		12,575
Deferred revenue, current		49,453		14,014
Deferred revenue, current, related party		1,072		789
Other current liabilities, related party		12,060		5,614
Other current liabilities		2,386		2,211
Total current liabilities		76,576		37,553
Deferred revenue, long-term		36,117		4,538
Deferred revenue, long-term, related party		2,586		3,106
Long-term debt, net of current portion		15,031		14,926
Operating lease liabilities		11,586		12,213
Other liabilities, related party		_		6,711
Other liabilities		1,523		1,490
Total liabilities		143,419		80,537
Commitments and contingencies (Note 10)		_		
Stockholders' equity				
Preferred stock, \$0.001 par value:				
Authorized: 2,000,000 shares at March 31, 2021 and December 31, 2020; issued and outstanding: 250 shares at March 31, 2021 and December 31, 2020		_		_
Common stock, \$0.001 par value:				
Authorized: 150,000,000 shares at March 31, 2021 and December 31, 2020; issued and outstanding: 56,082,931 shares at				
March 31, 2021 and 49,984,333 shares at December 31, 2020		56		50
Additional paid-in capital		404,116		328,314
Accumulated other comprehensive income		2		17
Accumulated deficit		(295,819)		(269,041)
Total stockholders' equity		108,355		59,340
Total liabilities and stockholders' equity	\$	251,774	\$	139,877



Source: Molecular Templates, Inc.