

Molecular Templates, Inc. Reports Fourth Quarter 2020 Financial Results

AUSTIN, Texas, March 18, 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 fourth quarter of 2020.

"In 2020 and early 2021, we made important progress by advancing our pipeline programs, establishing a new collaboration with a premier oncology partner, and strengthening our balance sheet with a successful equity financing," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Scientific Officer. "We now have four clinical stage programs: MT-5111 targeting HER2, TAK-169 targeting CD38 in co-development with Takeda, MT-6402 with antigen seeding targeting PD-L1, and MT-3724, for which we are working to resolve the FDA partial clinical hold. We expect to generate clinical data from multiple programs and advance our earlier stage programs in 2021, including filing an IND for an ETB targeting CTLA-4, preclinical data presentations on ETBs against new targets, and continued progress in our collaborations with Bristol Myers Squibb, Vertex, and Takeda."

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.
- MTEM has had three abstracts accepted for presentation at the upcoming American Association for Cancer Research (AACR) Annual Meeting 2021, taking 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. 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 1H21 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 present interim clinical results from the dose escalation portion of the MT-5111 Phase 1 study as of December 2020, at the AACR Annual Meeting April 10-15, 2021. 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)

- Takeda and MTEM are currently conducting a 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.
- In December 2020, preclinical TAK-169 data were presented at the 62nd ASH Annual Meeting and Exposition.

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.

MT-3724 (CD20 ETB)

 Since November 4, 2020, all MT-3724 clinical studies have been on partial clinical hold as ordered by the FDA following a treatment-related fatality in one subject who experienced Grade 5 CLS in the Phase 2 MT-3724 monotherapy study. As part of the overall investigation into the partial clinical hold on MT-3724, MTEM investigated MT-3724 product quality attributes. Based on the findings, MTEM submitted a partial clinical hold response to the FDA in February 2021 in which it proposed to implement new drug product manufacturing and release specifications.

- MTEM is working to address the partial clinical hold and MT-3724 product lot information requests from the FDA.
- In tandem, MTEM is actively evaluating the role of MT-3724 and CD20 as a target in MTEM's portfolio relative to other opportunities.

Research

- MTEM expects to file an IND application for an ETB targeting CTLA-4 in 4Q21.
- Several other ETB candidates are in preclinical development against targets including SLAMF-7 and CD45.
- 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 fourth quarter of 2020 was \$28.4 million, or \$0.57 per basic and diluted share. This compares with a net loss attributable to common shareholders of \$15.9 million, or \$0.41 per basic and diluted share, for the same period in 2019.

Revenues for the fourth quarter of 2020 were \$3.5 million, compared to \$6.2 million for the same period in 2019. Revenues for the fourth quarter of 2020 were comprised of revenues from collaborative research and development agreements with Takeda and Vertex. Total research and development expenses for the fourth quarter of 2020 were \$22.3 million, compared with \$16.6 million for the same period in 2019. Total general and administrative expenses for the fourth quarter of 2020 were \$7.1 million, compared with \$6.0 million for the same period in 2019.

As of December 31, 2020, MTEM's cash and investments totaled \$93.9 million. With the addition of the \$70 million upfront payment from Bristol Myers Squibb received in 1Q21 and the proceeds of the public equity offering completed in February 2021, 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 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 potential lifting of the partial clinical hold on Molecular Templates' MT-3724 clinical trials; our investigation into MT-3724 product attributes and potential plans for our MT-3724 studies; statements regarding the safety or potential efficacy of Molecular Templates' drug or biologic candidates; statements relating to the development of MT-3724, MT-5111, TAK-169, and MT-6402; the expected timing of submitting various IND applications and conducting studies and generating data; 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, Molecular Templates' ability to satisfactorily respond to requests from the FDA for further information and data regarding MT-3724 on the timeline expected or at all; successfully resolve the partial clinical hold with regard to MT-3724; 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. 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,				
		2020		2019		2020		2019
Research and development revenue - from related party	\$	1,605	\$	4,688	\$	6,567	\$	19,499
Research and development revenue - other		1,892		_		9,068		
Grant revenue		_		1,509		3,210		2,771
Total revenue		3,497		6,197		18,845		22,270
Operating expenses:						_		
Research and development		22,298		16,573		92,965		50,519
General and administrative		7,116		6,028		26,722		20,077
Loss on impairment of in-process research and development		_		_		_		22,123
Total operating expenses		29,414		22,601		119,687		92,719
Loss from operations		25,917		16,404		100,842		70,449
Interest and other income, net		103		873		1,028		2,323
Interest and other expense, net		(476)		(351)		(1,705)		(1,298)
Loss on Extinguishment of Debt		_		_		(1,237)		_
Loss on disposal of assets		(2,155)		_		(2,155)		_
Change in fair value of warrant liabilities		_		_		_		3
Loss before provision (benefit) for income taxes		28,445		15,882		104,911		69,421
Provision for income taxes		_		<u> </u>		5		<u> </u>
Net loss attributable to common shareholders	_	28,445	_	15,882		104,916		69,421
Net loss per share attributable to common shareholders:								
Basic and diluted	\$	0.57	\$	0.41	\$	2.20	\$	1.86
Weighted average number of shares used in net loss per share calculations:								
Basic and diluted		49,970,514		40,552,083		47,603,261		37,770,378

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

ASSETS Current assets: Cash and cash equivalents \$ 25,218 \$ 85,451 Marketable securities, current 68,667 39,633 Prepaid expenses 6,080 2,318 Grants revenue receivable Accounts receivable, related party In-process research and development - held for sale Other current assets Total current assets Marketable securities, non-current
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Marketable securities, non-current
4.540
Operating lease right-of-use assets
Property and equipment, net 22,254 18,158
Other assets 5,195 4,676
Total assets \$ 139,877 \$ 174,202
LIABILITIES AND STOCKHOLDERS' EQUITY
Current liabilities:
Accounts payable \$ 2,350 \$ 1,465
Accrued liabilities 12,575 14,544
Deferred revenue, current 14,014 8,511
Deferred revenue, current, related party 789 8,780
Other current liabilities, related party 5,614 —
Other current liabilities 2,211 2,501
Total current liabilities 37,553 35,801
Deferred revenue, long-term 4,538 18,944
Deferred revenue, long-term, related party 3,106 441
Long-term debt, net 14,926 2,940
Operating lease liabilities 12,213 11,682
Other liabilities, related party 6,711 —
Other liabilities 1,490 1,366
Total liabilities 80,537 71,174
Commitments and contingencies (Note 10)
Stockholders' equity
Preferred stock, \$0.001 par value:
Authorized: 2,000,000 shares at December 31, 2020 and
December 31, 2019; issued and outstanding: 250 shares at
December 31, 2020 and December 31, 2019 — — —
Common stock, \$0.001 par value:
Authorized: 150,000,000 shares at December 31, 2020 and
December 31, 2019; issued and outstanding: 49,984,333 shares at
December 31, 2020 and 45,589,157 shares at December 31, 2019 50 46
Additional paid-in capital 328,314 267,089
Accumulated other comprehensive income 17 18
Accumulated deficit (269,041) (164,125
Total stockholders' equity 59,340 103,028
Total liabilities and stockholders' equity \$ 139,877 \$ 174,202



Source: Molecular Templates, Inc.