May 12, 2022

Molecular Templates, Inc. Reports First Quarter 2022 Financial Results

AUSTIN, Texas, May 12, 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 first quarter of 2022.

“We continue to make meaningful progress in advancing our pipeline of ETBs,” said Eric Poma, Ph.D., Chief Executive and Chief Scientific Officer of Molecular Templates. “We recently commenced dosing in Cohort 3 of our Phase 1 study of MT-6402 in PD-L1+ patients. We intend to report additional data from this study in the second half of the year. Dose finding in the MT-5111 and MT-0169 programs is ongoing with clinical data expected this year. We look forward to continued momentum across our pipeline in 2022, including filing an IND for MT-8421, our ETB targeting CTLA-4, and advancing our earlier stage pipeline of ETBs 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 hosted a webinar on MT-6402 (PD-L1 ETB with Antigen Seeding Technology) with David Spigel, M.D. of the Sarah Cannon Research Institute on April 13. A replay of the event (including slides) can be accessed here.
- Abstracts on MT-6402 and MT-5111 (HER2 ETB) have been accepted for presentation at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, to take place June 3-7, 2022, in Chicago, IL.
- Gabriela Gruia, M.D. appointed to Board of Directors.
- Megan Filoon promoted to General Counsel.

Immuno-oncology ETBs:

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

- Patient enrollment continues in the Phase 1 study of MT-6402 which began in July 2021. MT-6402 is a 3rd generation ETB 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 (TME) are eligible for enrollment.

- As of March 2022, twelve patients with relapsed/refractory tumors that express PD-L1 have been treated to date across two dose cohorts: 16 mcg/kg (n=6) and 24 mcg/kg (n=6). Dosing continues with three patients currently enrolled in the 32 mcg/kg cohort (cohort 3).
- One patient in cohort 1 (16 mcg/kg) with non-small cell lung cancer (NSCLC) that had progressed after prior checkpoint therapy (PD-1 and CTLA-4) 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.
- The 16 mcg/kg cohort was completed with no dose-limiting toxicities (DLTs) observed. One DLT was observed in a single patient in cohort 2 (24 mcg/kg). The patient experienced dermatitis that resolved rapidly with systemic steroids. The patient was rechallenged without incident at 24 mcg/kg. No other DLTs have been reported.
- Following determination of the maximum tolerated dose (MTD), MTEM plans expansion cohorts to evaluate MT-6402 as a monotherapy in tumor-specific and PD-L1 positive basket tumor cohorts.
- 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, including monocyte depletion and T cell activation, potentially in a dose-dependent manner.
- These PD effects associated with immune activation were seen across the majority of patients irrespective of HLA type or level of tumor PD-L1 staining. The patient that demonstrated tumor regression was one of two patients treated with high tumor PD-L1 expression and may represent engagement of direct tumor cell-kill and antigen seeding.

MT-8421 (CTLA-4 ETB)

- Preclinical data from MTEM's CTLA-4 program were featured in a poster at the AACR annual meeting held April 8-13, 2022. In a transgenic mouse model expressing human CTLA-4 and bearing syngeneic subcutaneous tumors, MT-8421 treatment depleted immune suppressive regulatory T cells (Tregs) in the TME.
- MT-8421 was well tolerated in a non-human primate toxicology study and achieved serum levels well-above projected IC50 concentrations for Tregs in the TME.
- IND filing for MT-8421 is expected in 2H22, with clinical studies expected to commence in 2023.
- MT-6402 and MT-8421 represent MTEM's unique approach to immuno-oncology based on dismantling the TME through direct cell-kill of tumor and immune cells and not just the blocking of ligand-ligand interactions seen with current antibody therapeutics.

Research

- MTEM continues to expand its unique approach to immuno-oncology targets with lead optimization on a TIGIT-targeting ETB on-going and additional exploration around new immuno-oncology targets.

Targeted Solid Tumor ETBs:

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. Enrollment in the 17 mcg/kg cohort has been initiated.
- Dose escalation will continue to determine the MTD, while the breast cancer expansion cohort collects efficacy and safety data.
- No signs of capillary leak syndrome (CLS) or significant cardiotoxicity have been observed to date with MT-5111.

Research

- Lead optimization on a 3rd generation ETB targeting TROP-2 continues.

Hematologic Malignancy Targeted ETBs:

MT-0169 (CD38 ETB)

- The revised protocol for the ongoing Phase 1 study in patients with relapsed/refractory multiple myeloma or non-Hodgkin's lymphoma is now open. The revised protocol will 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.
- MTEM is opening new sites for the Phase 1 study and anticipates enrollment beginning in the second quarter of 2022.

Research

- Lead optimization on BCMA, SLAMF-7, and CD45 continues.

Financial Results

The net loss attributable to common shareholders for the first quarter of 2022 was $21.6 million, or $0.38 per basic and diluted share. This compares with a net loss attributable to common shareholders of $26.8 million, or $0.51 per basic and diluted share, for the same period in 2021.

Revenues for the first quarter of 2022 were $8.5 million, compared to $3.2 million for the same period in 2021. Revenues for the first quarter of 2022 were comprised of revenues from collaborative research and development agreements with Takeda and Bristol Myers Squibb.

Total research and development expenses for the first quarter of 2022 were $21.5 million, compared with $21.4 million for the same period in 2021. Total general and administrative expenses for the first quarter of 2022 were $7.6 million, compared with $8.2 million for the same period in 2021.

As of March 31, 2022, MTEM's cash and investments totaled $124.5 million. MTEM's current cash and investments are expected to fund operations to the end of 2023.

For more details on MTEM's financial results for the first quarter 2022, refer to Form 10Q filed with the SEC.

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-6402, MT-5111, MT-0169, and MT-8421 and next-generation ETBs; the expected timing for submitting various IND applications and conducting studies, opening sites and generating data; the expected participation and presentation at upcoming conferences; the expected timing for providing updates on MT-6402, MT-5111, MT-0169, and MT-8421, including any pre-clinical data as well as Molecular Templates' earlier stage pipeline of ETBs; 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 March 31,	
	2022	2021
Research and development revenue, related party	$ —	$ 237
Research and development revenue, other	8,486	2,983
Total revenue	8,486	3,220
Operating expenses:		
Research and development	21,497	21,368
General and administrative	7,620	8,181
Total operating expenses	29,117	29,549
Loss from operations	20,631	26,329
Interest and other income, net	70	52
Interest and other expense, net	(1,050)	(501)
Net loss	21,611	26,778
Net loss attributable to common shareholders	$ 21,611	$ 26,778
Net loss per share attributable to common shareholders:		
Basic and diluted	$ 0.38	$ 0.51
Weighted average number of shares used in net loss per share calculations:		
Basic and diluted	56,305,049	52,564,628

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

	March 31, 2022(unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,572	$ 24,983
Marketable securities, current	104,947	118,061
Prepaid expenses	2,615	3,917
Other current assets	5,251	1,254
Total current assets	132,385	148,215
Marketable securities, non-current	—	8,986
Operating lease right-of-use assets	8,206	8,608
Property and equipment, net	18,634	19,309
Other assets	3,940	7,244
Total assets	$ 163,165	$ 192,362
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ —	$ 1,612
Accrued liabilities	7,905	9,515
Deferred revenue, current	34,586	32,937
Other current liabilities	2,533	2,606
Total current liabilities	45,024	46,670
Deferred revenue, long-term	24,252	33,350
Long-term debt, net of current portion	35,737	35,491
Operating lease liabilities	9,009	9,564
Other liabilities	1,661	1,625
Total liabilities	115,683	126,700
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at March 31, 2022 and December 31, 2021; issued and outstanding: 250 shares at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares at March 31, 2022 and December 31, 2021; issued and outstanding: 56,305,049 shares at March 31, 2022 and 56,305,049 shares at December 31, 2021	56	56
Additional paid-in capital	421,386	417,704
Accumulated other comprehensive loss	(299)	(48)
Accumulated deficit	(373,661)	(352,050)
Total stockholders' equity	47,482	65,662
Total liabilities and stockholders' equity	$ 163,165	$ 192,362

Source: Molecular Templates, Inc.