August 11, 2022

Molecular Templates, Inc. Reports Second Quarter 2022 Financial Results

AUSTIN, Texas, Aug. 11, 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), to create novel therapies with potent and differentiated mechanisms of action for cancer and other serious diseases, today reported financial results and business updates for the second quarter of 2022.

“We are pleased with the progress we are making to advance our potent ETB pipeline of drug candidates which are highly differentiated from Antibody-Drug Conjugates (ADCs), each with a substantial and unique value proposition,” said Eric Poma, PhD., Chief Executive and Chief Scientific Officer of Molecular Templates. “We presented six posters on our programs at the 2022 American Association for Cancer Research (AACR) Annual Meeting, as well as two posters on MT-6402 (PD-L1 ETB with Antigen Seeding Technology) and MT-5111 at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, and we look forward to reporting updates in the second half of the year as we plan to expand our Phase 1 study of MT-6402 in PD-L1+ patients and continue dose-finding in the MT-5111 and MT-0169 programs. We remain on track toward our anticipated IND submission for MT-8421 (CTLA-4 ETB with unique I/O approach) and are executing on additional novel ETB programs targeting TROP2, TIGIT, and BCMA. We also continue to move forward with our collaboration agreement with Bristol Myers Squibb.”

Company Highlights and Upcoming Milestones

Corporate

- MTEM expects to provide periodic updates on MT-6402, MT-8421, MT-5111, and MT-0169 throughout 2022.
- Data presentations are expected at the 2022 Society for Immunotherapy of Cancer (SITC) and 2022 San Antonio Breast Cancer Symposium (SABC).
- MTEM expects to file an IND for MT-8421 (CTLA-4 ETB) at year-end 2022.
- MTEM is advancing momentum on the development of its additional ETB candidates (TROP2, TIGIT, and BCMA).
- MTEM presented six posters on its pipeline programs at the 2022 American Association for Cancer Research (AACR) Annual Meeting, which took place April 8 – April 13, 2022 in New Orleans, LA. Copies of the posters presented at AACR can be accessed here.
- MTEM provided a virtual company presentation at H.C. Wainwright Global Investment Conference, which took place May 23-26, 2022.
- MTEM presented two posters on MT-6402 (PD-L1 ETB with Antigen Seeding Technology) and MT-5111 (HER2 ETB) at the 2022 American Society of Clinical

Oncology (ASCO) Annual Meeting, which took place June 3-7, 2022 in Chicago, IL. Copies of the posters presented at ASCO can be accessed here.
- MTEM held a fireside chat at Jefferies Healthcare Conference, which took place June 9, 2022 in New York, NY.
- MTEM will provide a virtual company presentation and participate in-person at HC Wainwright 24th Annual Global Investment Conference September 12-14, 2022 in New York, NY.
- MTEM will participate at the Morgan Stanley 20th Annual Global Healthcare Conference September 12-14, 2022 in New York, NY.
- Dr. Grace Kim was appointed Head of Investor Relations.

ETB Technology

ETBs represent a novel platform for therapeutic development with unique biology. In contrast to Antibody Drug Conjugates (ADCs), ETBs leverage differentiated biology and MoAs which include internalizing or non-internalizing targets, endosomal escape with self-routing to cytosol, enzymatic ribosome inactivation, and cytosolic/ER delivery. ETBs can also alter the immunophenotype of tumor cells through Antigen Seeding technology. MTEM is developing ETBs against validated targets where its differentiated biology may allow for efficacy in a relapsed/refractory setting.

Immuno-Oncology ETBs:

MT-6402 and MT-8421 represent MTEM's unique approach to immuno-oncology based on dismantling the TME through direct cell-kill of immune cells rather than blocking of ligand-ligand interactions as seen with current antibody therapeutics.

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

- MT-6402 is a 3rd generation ETB designed to induce potent anti-tumor activity via PD-L1 targeting with unique effects that include the dismantling of the tumor microenvironment by directly destroying PD-L1+ immune cells, direct cell-kill of PD-L1+ tumor cells, and immunophenotype alteration of PD-L1+ tumor cells in HLA-A*02 /CMV+ patients.
- The Phase 1 study of MT-6402 began in July 2021. It is 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 (TME) are eligible for enrollment.
- As of August 5, 2022, 16 patients with relapsed/refractory tumors that express PD-L1 have been treated to date across three dose cohorts: 16 mcg/kg (n=6), 24 mcg/kg (n=6) and 32 mcg/kg (n=4). Dosing continues with two patients currently enrolled in cohort 4 at 42 mcg/kg.
- At the 24 mcg/kg dose, there was a grade 2 dermatitis that resolved rapidly with oral steroids. The patient reported mild pruritus and was rechallenged without incident at the same dose. No other DLTs have been reported. Cohort 3 (32 mcg/kg) was completed with no DLTs. Cohort 4 (42 mcg/kg) has been initiated.
- One patient in Cohort 1 (16 mcg/kg) with non-small cell lung cancer (NSCLC) demonstrated tumor regression. This patient was one of two patients with high tumor PD-L1 expression and was also HLA-A*02/ CMV+. Another patient with modest PD-L1

expression of 10% Tumor Proportion Score has remained on treatment with stable disease for greater than nine months.
- Following determination of the maximum tolerated dose (MTD), MTEM will plan expansion cohorts to evaluate MT-6402, both as a monotherapy and as a combination approach with a PD-1 inhibitor in tumor-specific and PD-L1 positive basket tumor cohorts.
- MTEM continues to observe pharmacodynamic (PD) effects not seen with PD-L1 antibodies and consistent with the dismantling of the TME including PD-L1+ immune cell depletion and T cell activation, as well as cytokine changes in TNF-α, IL-2, and vascular endothelial growth factor (VEGF) in all dose escalation cohorts evaluated to date. The extent and timing of these PD effects appear dose-related with patients in the 24 and 32 mcg/kg cohorts generally showing a more rapid and profound PD effect, including monocyte depletion and T cell activation, potentially in a dose-dependent manner.
- PD effects associated with immune activation were seen across the majority of patients irrespective of HLA genotype or level of tumor or immune cell PD-L1 staining. The patient who 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 IC_{50} concentrations for Tregs in the TME.
- An IND filing for MT-8421 is expected year-end 2022, with clinical studies expected to commence in the second quarter of 2023.
- The ETB approach includes potent destruction of CTLA-4+ Tregs via enzymatic ribosome destruction, and the mechanism of cell kill is independent of the TME. There is also preferential activity on high CTLA-4 expressing Tregs in the TME.

Research

- MTEM continues to expand its unique approach to immuno-oncology targets with lead optimization ongoing for a TIGIT-targeting ETB and additional exploration around new immuno-oncology targets. TIGIT ETB candidates deplete TIGIT+ immune cells ex vivo and in vivo. Sub-nM potency on TIGIT+ cell lines and reversal of Treg mediated suppression of T-cell proliferation have been seen along with depletion of Tregs in murine TME.

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 was initiated in November 2021 at

a dose of 10 mcg/kg.
- As of June 2022, 35 patients have been treated with MT-5111 across nine dose escalation cohorts ranging from 0.5 mcg/kg to 17 mcg/kg without any DLTs, including two patients who were treated for six months or longer.
- Enrollment in the 23 mcg/kg cohort has been initiated.
- Six patients have been treated with breast cancer on the expansion cohort at 10 mcg/kg; three patients have remained on treatment for greater than 28, 16, and 10 weeks, respectively, with stable disease.
- One patient with gastric cancer experienced a grade 3 rash at a dose of 23 mcg/kg. The rash subsided to grade 1 with topical steroids and the patient continues to be treated at the same dose. Dose escalation will continue to determine the MTD while the breast cancer expansion cohort collects efficacy and safety data.
- To date, no cases of clinically significant cardiotoxicity have been observed in human subjects who have been dosed with MT-5111.
- Serum concentration of MT-5111 showed predictable and dose-proportional increasing exposure in the last four evaluable dose cohorts.
- Higher MT-5111 doses (6.75 mcg/kg and above) appear to saturate circulating soluble HER2 (sHER2) receptors with patients' sHER2 levels stabilizing or decreasing at higher doses.

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 (MM) or non-Hodgkin's lymphoma is now open. One patient with MM has started treatment at 5 mcg/kg. The revised protocol explores a lower dose of MT-0169 to reduce the risk of adverse events observed at the initial dose of 50 mcg/kg and to enable patients to continue MT-0169 therapy for a longer duration that may drive tumor benefit. The robust and rapid NK cell depletion that was observed at the starting dose of 50 mcg/kg is expected to be observed at lower doses, based upon IC_{50} *in vitro* data.
- MTEM is opening new sites for the Phase 1 study and enrollment resumed in July 2022.

Research

- Lead optimization on BCMA continues.

Financial Results

The net loss attributable to common shareholders for the second quarter of 2022 was $24.4 million, or $0.43 per basic and diluted share. This compares with a net loss attributable to common shareholders of $15.6 million, or $0.28 per basic and diluted share, for the same period in 2021.

Revenues for the second quarter of 2022 were $4.4 million, compared to $15.1 million for the same period in 2021. Revenues for the second quarter of 2022 were comprised of revenues from collaborative research and development agreements with Bristol Myers Squibb.

Total research and development expenses for the second quarter of 2022 were $21.4 million, compared with $21.1 million for the same period in 2021. Total general and administrative expenses for the second quarter of 2022 were $6.6 million, compared with $8.9 million for the same period in 2021.

As of June 30, 2022, MTEM's cash and investments totaled $104.4 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 second 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 MT-6402, MT-5111, MT-0169, and MT-8421 and 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; statements relating to the progress of our collaboration agreement; 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 from ADCs that may address some of the limitations associated with currently available therapeutics for cancer and other serious diseases.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development revenue, related party	$ —	$ 12,899	$ —	$ 13,136
Research and development revenue, other	4,417	2,235	12,903	5,218
Total revenue	4,417	15,134	12,903	18,354
Operating expenses:				
Research and development	21,690	21,127	43,187	42,447
General and administrative	6,566	8,922	14,186	17,151
Total operating expenses	28,256	30,049	57,373	59,598
Loss from operations	23,839	14,915	44,470	41,244
Interest and other income, net	186	81	256	133
Interest and other expense, net	(1,092)	(767)	(2,142)	(1,268)
Net loss	24,745	15,601	46,356	42,379
Net loss attributable to common shareholders	$ 24,745	$ 15,601	$ 46,356	$ 42,379
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 0.44	$ 0.28	$ 0.82	$ 0.78
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	56,329,585	56,096,238	56,317,194	54,340,173

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

	June 30, 2022(unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,936	$ 24,983
Marketable securities, current	77,489	118,061
Prepaid expenses	2,395	3,917
Other current assets	4,271	1,254
Total current assets	111,091	148,215
Marketable securities, non-current	—	8,986
Operating lease right-of-use assets	7,794	8,608
Property and equipment, net	17,913	19,309
Other assets	4,006	7,244
Total assets	$ 140,804	$ 192,362
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,641	$ 1,612
Accrued liabilities	9,529	9,515
Deferred revenue, current	32,984	32,937
Other current liabilities	2,459	2,606
Total current liabilities	46,613	46,670
Deferred revenue, long-term	22,662	33,350
Long-term debt, net of current portion	35,675	35,491
Operating lease liabilities	8,444	9,564
Other liabilities	1,698	1,625
Total liabilities	115,092	126,700
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value: Authorized: 2,000,000 shares at June 30, 2022 and December 31, 2021; issued and outstanding: 250 shares at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value: Authorized: 150,000,000 shares at June 30, 2022 and December 31, 2021; issued and outstanding: 56,339,558 shares at June 30, 2022 and 56,305,049 shares at December 31, 2021	56	56
Additional paid-in capital	424,392	417,704
Accumulated other comprehensive loss	(330)	(48)
Accumulated deficit	(398,406)	(352,050)
Total stockholders' equity	25,712	65,662
Total liabilities and stockholders' equity	$ 140,804	$ 192,362

Source: Molecular Templates, Inc.