November 10, 2022

Molecular Templates, Inc. Reports Third Quarter 2022 Financial Results

AUSTIN, Texas, Nov. 10, 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 third quarter of 2022.

“We are excited with the progress we continue to make across all our clinical and pre-clinical programs. We have now seen evidence of monotherapy clinical activity with MT-6402, MT-5111, and MT-0169 in heavily pretreated relapsed/refractory patients -- in both solid and hematological cancer settings -- demonstrating the broad potential utility of this novel scaffold,” said Eric Poma, PhD., Chief Executive and Chief Scientific Officer of Molecular Templates. “We look forward to providing further updates on our MT-6402, MT-5111, and MT-0169 programs throughout 2023 and look forward to our anticipated IND submission for MT-8421 all while we continue to advance our development of additional ETB candidates targeting TROP2, TIGIT, and BCMA.”

Company Highlights and Upcoming Milestones

Corporate

- MTEM expects to provide periodic updates on MT-6402, MT-5111, MT-8421, and MT-0169 throughout 2023.
- Dose escalation continues with MT-6402 with dose dependent pharmacodynamic (PD) effects observed. One patient in cohort 1 (16 mcg/kg) with non-small cell lung cancer (NSCLC) and osseous metastases demonstrated tumor regression. This patient is the only patient treated thus far with high tumor PD-L1 expression and HLA-A*02/ CMV+.
- MT-5111 has declared Maximum Tolerated Dose (MTD) at 23 mcg/kg with a dose limiting toxicity (DLT) of grade 3 rash. The HER2-positive breast cancer (BC) dose expansion cohort (DEC) continues to enroll patients at a dose of 10 mcg/kg. Three of five evaluable BC patients treated at 10 mcg/kg have had prolonged Stable Disease for 40, 22, and 22 weeks, respectively. One of the patients treated for 22 weeks has experienced a 43% reduction in mediastinal lymphadenopathy and a halt in the growth of her pulmonary lesions. Overall, the patient has had a 14% reduction in index lesions. This patient has been previously treated with multiple HER2-targeting therapies including trastuzumab, pertuzumab, trastuzumab emtasine, lapatinib, trastuzumab deruxtecan, and tucatinib.
- MT-0169 completed the 5 mcg/kg dose escalation cohort (N=4) without any cardiac adverse events (AEs) or DLTs and is enrolling at 10 mcg/kg. One patient with IgA myeloma treated at 5 mcg/kg has had a marked reduction in IgA serum protein,

conversion from immunofixation positive to negative and marked improvement of hemoglobin to normal values, demonstrating at least a Partial Response. A PET scan is pending to determine if the patient is in a Complete Response.
- Of the over 80 patients treated across MTEM's three clinical programs to date, there has been no instance of capillary leak syndrome (CLS). One patient treated at 63 mcg/kg with MT-6402 showed a grade 2 decrease in albumin that may potentially represent a subclinical manifestation of CLS.
- All toxicities seen to date appear to be target-mediated and unrelated to the underlying scaffold.

ETB Technology

ETBs represent a novel platform with unique biology for therapeutic development in oncology. ETBs have the target specificity of antibodies, can force their own internalization, even against non-internalizing receptors, and can induce tumor cell death through the novel mechanism of enzymatic and irreversible ribosomal destruction. Because of this unique biology, ETBs to targets like HER2 and CD38 have the potential to drive clinical benefit in patients that have progressed after all available therapeutics. ETBs also represent a unique approach to immuno-oncology. Unlike current approaches to PD-L1 that only block the steric interaction of PD-1 and PD-L1, MT-6402, MTEM's ETB targeting PD-L1, is designed to directly kill PD-L1+ tumors cells, destroy immune cells that inhibit T-cell function and propagate tumor growth, and alter the immunophenotype of tumor cells.

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

- The Phase 1 study of MT-6402 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 TME are eligible for enrollment, irrespective of HLA genotype or CMV status.
- As of November 2022, 19 patients with relapsed/refractory tumors that express PD-L1 have been treated across four dose cohorts: 16 mcg/kg (n=6), 24 mcg/kg (n=6), 32 mcg/kg (n=4), and 42 mcg/kg (n=3). One DLT of grade 2 rash was observed in cohort 2 whereas no DLTs were reported in cohorts 1, 3 and 4. Enrollment continues in cohort 5 at 63 mcg/kg.
- One patient in cohort 1 (16 mcg/kg) with NSCLC demonstrated tumor regression of osseous metastases. This patient is the only patient treated thus far with high tumor PD-L1 expression and who is also HLA-A*02/ CMV+.
- MTEM continues to observe 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-dependent with higher dose levels showing more rapid and profound PD effects, including MDSC depletion and T cell activation. These effects were seen across the majority of patients irrespective of HLA genotype or level of tumor or immune cell PD-L1 staining.
- Treatment-related AEs including immune related AEs have been largely restricted to grade 1-2.

MT-5111 (HER2 ETB)

- As of November 2022, the Phase 1 study of MT-5111 has enrolled 48 patients across 10 dose escalation cohorts ranging from 0.5 mcg/kg to 23 mcg/kg. One DLT of grade 3 acneiform rash was observed at 23 mcg/kg, which improved to grade 1 with topical steroids, and the patient continued treatment at the same dose. 23 mcg/kg has been declared the MTD.
- Serum concentration of MT-5111 showed predictable and dose-proportional increasing exposure starting at 6.75 mcg/kg doses and higher.
- The HER2-positive BC DEC continues to enroll patients at a dose of 10 mcg/kg. Six patients have been treated, three of whom for 40, 22, and 22 weeks, respectively, at 10 mcg/kg.
- One of the patients treated for 22 weeks came on study with two nodal lesions and two non-nodal necrotic pulmonary lesions. The patient has seen a continued reduction in her nodal lesions while on therapy with a 43% reduction in mediastinal lymphadenopathy and a halt in the growth of her pulmonary lesions. Overall, the patient has had a 14% reduction in index lesions. This patient has been previously treated with multiple HER2-targeting therapies including trastuzumab, pertuzumab, trastuzumab emtasine, lapatinib, trastuzumab deruxtecan, and tucatinib. The next monotherapy cohort for BC patients is planned at 17 mcg/kg.
- No clinically significant cardiac AEs have been observed at any dose; grade 1 hs-troponin elevations have been observed at various doses.

MT-0169 (CD38 ETB)

- The Phase 1 study in patients with relapsed/refractory multiple myeloma (MM) or non-Hodgkin's lymphoma explores MT-0169 at doses lower than the initial dose of 50 mcg/kg to reduce the risk of AEs and to enable patients to continue MT-0169 therapy for a longer duration that may drive tumor benefit.
- The 5 mcg/kg cohort completed recruitment (N=4) and analysis with no related AEs higher than grade 1. CD38+ Natural Killer (NK) cell depletion was observed in cycle 1 and in cycle 2 for patients continuing therapy. Nadir levels of NK cells were delayed and lower in magnitude than observed at 50 mcg/kg. Enrollment at 10 mcg/kg has commenced.
- One patient with IgA myeloma treated at 5 mcg/kg has had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative and marked improvement of hemoglobin to normal values, demonstrating at least a Partial Response. A PET scan is pending to determine if the patient is in a Complete Response.

Research and Development

- Preclinical data from MTEM's MT-8421 program targeting CTLA-4 was featured in an abstract at the 2022 Society for Immunotherapy of Cancer (SITC) annual meeting held November 8-12, 2022, in Boston, Massachusetts. Clinical studies for MT-8421 are expected to commence in mid-2023.
- MTEM continues to expand its unique approach to immuno-oncology targets with lead optimization ongoing for several targets.
- Lead optimization continues on ETBs targeting TROP-2 incorporating Antigen Seeding Technology, a TIGIT-targeting ETB and BCMA.

Upcoming Conferences

- MTEM will present four posters (736, 764, 817, and 1379) and provide an in-person R&D Day presentation at the SITC annual meeting, Friday, November 11, 2022, 11:30am – 12:30pm ET. SITC posters can be accessed via MTEM's corporate website. The webcast can be accessed here.
- MTEM will present a fireside chat at the virtual ISI HealthCONx Conference, Wednesday, November 30, 2022, at 9:15am ET. The webcast will be live-streamed and can be accessed here.
- MTEM will present at the 2022 San Antonio Breast Cancer Symposium (SABCS) taking place December 6 – December 10, 2022, in San Antonio, Texas.
- MTEM will participate at the American Society of Hematology's 64th annual meeting taking place December 10 – 13, 2022 in New Orleans, Louisiana. One-on-one meetings may be scheduled directly with MTEM.

Financial Results

The net loss attributable to common shareholders for the third quarter of 2022 was $24.6 million, or $0.44 per basic and diluted share. This compares with a net loss attributable to common shareholders of $30.4 million, or $0.54 per basic and diluted share, for the same period in 2021.

Revenues for the third quarter of 2022 were $4.2 million, compared to $2.4 million for the same period in 2021. Revenues for the third quarter of 2022 were comprised of revenues from collaborative research and development agreements with Bristol Myers Squibb.

Total research and development expenses for the third quarter of 2022 were $22.0 million, compared with $22.9 million for the same period in 2021. Total general and administrative expenses for the third quarter of 2022 were $5.9 million, compared with $9.0 million for the same period in 2021.

As of September 30, 2022, MTEM's cash and investments totaled $79.4 million.

For more details on MTEM's financial results for the third quarter 2022, refer to Form 10-Q 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 or clinical data as well as Molecular Templates' 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 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development revenue, related party	$ —	$ —	$ —	$ 13,136
Research and development revenue, other	4,240	2,379	17,143	7,597
Total revenue	4,240	2,379	17,143	20,733
Operating expenses:				
Research and development	21,973	22,881	64,835	65,328
General and administrative	5,934	9,027	20,120	26,178
Total operating expenses	27,907	31,908	84,955	91,506
Loss from operations	23,667	29,529	67,812	70,773
Interest and other income, net	307	175	563	308
Interest and other expense, net	(1,252)	(1,033)	(3,394)	(2,301)
Net loss	24,612	30,387	70,643	72,766
Provision for income taxes	26	—	26	—
Net loss attributable to common shareholders	$ 24,638	$ 30,387	$ 70,669	$ 72,766
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 0.44	$ 0.54	$ 1.25	$ 1.32
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	56,350,858	56,174,644	56,328,664	54,958,365

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

	September 30, 2022(unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,277	$ 24,983
Marketable securities, current	57,168	118,061
Prepaid expenses	3,729	3,917
Other current assets	4,011	1,254
Total current assets	87,185	148,215
Marketable securities, non-current	—	8,986
Operating lease right-of-use assets	11,120	8,608
Property and equipment, net	16,347	19,309
Other assets	3,994	7,244
Total assets	$ 118,646	$ 192,362
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,085	$ 1,612
Accrued liabilities	8,890	9,515
Deferred revenue, current	38,290	32,937
Other current liabilities	1,957	2,606
Total current liabilities	50,222	46,670
Deferred revenue, long-term	14,641	33,350
Long-term debt, net of current portion	35,940	35,491
Operating lease liabilities	12,422	9,564
Other liabilities	1,269	1,625
Total liabilities	114,494	126,700
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at September 30, 2022 and December 31, 2021; issued and outstanding: 250 shares at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares at September 30, 2022 and December 31, 2021; issued and outstanding: 56,351,647 shares at September 30, 2022 and 56,305,049 shares at December 31, 2021	56	56
Additional paid-in capital	427,042	417,704
Accumulated other comprehensive loss	(227)	(48)
Accumulated deficit	(422,719)	(352,050)
Total stockholders' equity	4,152	65,662
Total liabilities and stockholders' equity	$ 118,646	$ 192,362

Source: Molecular Templates, Inc.