March 30, 2023

# Molecular Templates, Inc. Reports Fourth Quarter 2022 Financial Results and Business Update

## Announces strategic reprioritization to focus on clinical development of MT-6402, MT-8421, and MT-0169, and preclinical activities related to BMS collaboration, and related workforce reduction

AUSTIN, Texas, March 30, 2023 (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 differentiated mechanisms of action for cancer, today reported financial results for the fourth quarter and full year ended December 31, 2022. MTEM also announced a strategic reprioritization and corresponding reduction in workforce, in order to focus on its core clinical development programs and extend its financial runway.

**Strategic Reprioritization and Cost-Saving Measures**

On March 29, 2023, the Board of Directors of MTEM approved a strategic reprioritization and corresponding reduction in workforce, designed to focus on the clinical development programs for MT-6402 (PD-L1), MT-8421 (CTLA-4), and MT-0169 (CD38), and preclinical activities related to MTEM's collaboration with Bristol Myers Squibb. This restructuring will reduce MTEM's workforce by approximately 50%, result in the cessation of the MT-5111 (HER2) clinical development program, and focus the majority of MTEM's preclinical efforts around activities related to the Bristol Myers Squibb collaboration.

Eric Poma, PhD., Chief Executive and Chief Scientific Officer of MTEM, stated: "These cost-savings measures are a difficult, but necessary, step for MTEM to take in order to continue pursuing the development of these promising programs. We thank all our employees who have worked so hard to bring these programs this far, and we will continue this important work with our refocused strategy and available resources." Dr. Poma added, "We have now seen evidence of monotherapy clinical activity with MT-6402 through two separate mechanisms of action unique to immuno-oncology: the alteration of tumor immunophenotype and the dismantling of the tumor microenvironment ('TME'). We recently announced the FDA's acceptance of our Investigational New Drug Application ('IND') for MT-8421, a new approach to CTLA-4 that we believe can potently deplete Tregs in the TME without driving immune-related adverse events ('irAEs'). We look forward to providing further updates on our MT-6402, MT-8421 and MT-0169 programs throughout 2023."

**Company Highlights**

- MTEM expects to provide periodic updates on MT-6402, MT-8421, and MT-0169 throughout 2023.
- Clinical data for each program has demonstrated novel mechanisms of action, unique pharmacodynamic ("PD") effects, and single agent activity in heavily relapsed / refractory patients across immuno-oncology, hematologic, and solid tumor indications.
- Dose escalation continues for MT-6402. MTEM observed dose-dependent PD effects not seen with PD-(L)1 antibodies and consistent with T-cell activation and TME dismantling. Maximal MDSC depletion was observed at 63 mcg/kg, the highest dose cleared to date. PD effects were seen across patients, irrespective of HLA genotype or level of tumor or immune cell PD-L1 staining.
- Seven patients were evaluable for radiographic assessment at the end of cycle 2 in the 63 mcg/kg cohort for MT-6402. One patient with nasopharynx squamous cell carcinoma in this cohort had a PR (RECIST) with a 63% reduction in the index lesion after cycle 2 which was maintained and confirmed at the end of cycle 4 (66% reduction). The patient remains on study.
- One patient in cohort 1 (16 mcg/kg) for MT-6402 with non-small cell lung cancer ("NSCLC") demonstrated resolution of three osseous lesions and a reduction in uptake in the remaining lesion. This patient remained on treatment for approximately 8 months.
- An IND for MT-8421 was accepted on March 8, 2023, with the first-in-human phase I study anticipated by mid-year 2023. MT-8421 targets CTLA-4-expressing Tregs in the TME for elimination without affecting Tregs in the periphery.
- Dose escalation continues for MT-0169. MT-0169 completed the 5 mcg/kg dose escalation cohort (N=4) and the 10 mcg/kg dose escalation cohort (N=3) without any cardiac AEs or dose-limiting toxicities ("DLTs") and is enrolling at 15 mcg/kg. A Very Good Partial Response ("VGPR") was seen in a patient with extramedullary IgA myeloma treated at 5 mcg/kg which improved to a stringent Complete Response at cycle 8. The patient remains on study.
- Of the over 100 patients treated across MTEM's three clinical programs utilizing our de-immunized scaffold to date, there have been no instances of capillary leak syndrome or other manifestations of innate immunity observed.
- Nearly all toxicities seen to date appear to be target-mediated with no non-specific scaffold effects noted, apart from occasional episodes of an infusion related reaction. No instances of off-target hematologic toxicity, interstitial lung disease, hepatic toxicity, or ocular toxicity common with antibody-drug conjugates have been observed.
- The ETB platform continues to demonstrate clinical validation in terms of both safety and efficacy.

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

- MT-6402 was designed to activate T-cells through direct cell-kill of immunosuppressive PD-L1+ immune cells.
- In addition, MT-6402 can deliver and induce the presentation of an MHC class I CMV antigen on tumor cells (antigen seeding mechanism of action) for pre-existing CD8 T-cell recognition and destruction in HLA-A*02/CMV+ patients with high PD-L1 expression on their tumors.
- MT-6402 continues to demonstrate PD effects and monotherapy activity in heavily pre-treated checkpoint therapy experienced patients.
- Dose escalation continues in the MT-6402 phase I study in relapsed/refractory solid

tumor patients with PD-L1-expressing tumors and/or PD-L1 expressing immune cells in the TME.

Highlights from the on-going Phase I study include:

- MTEM continues to observe PD effects not seen with PD-(L)1 antibodies and consistent with T-cell activation and TME dismantling. Maximal MDSC depletion was observed at 63 mcg/kg, the highest dose cleared to date. PD effects were seen across patients, irrespective of HLA genotype or level of tumor or immune cell PD-L1 staining.
- Seven patients were evaluable for radiographic assessment at the end of cycle 2 in the 63 mcg/kg cohort. One patient in this cohort had a PR (RECIST) with a 63% reduction in the index lesion after cycle 2 which was maintained and confirmed at the end of cycle 4. This is a patient with metastatic squamous cell nasopharynx carcinoma ("NPC") with disease progression after radiation therapy, chemotherapy, and pembrolizumab who had 2% PD-L1 expression and is not HLA-A*02, suggesting that the response is due to T-cell activation through the clearance of PD-L1+ immune cells, a novel mechanism in immuno-oncology. The patient showed a >250% increase in their CD8/CD4 T-cell ratio. The patient remains on study in the fifth month of therapy.
- One patient in cohort 1 (16 mcg/kg) with NSCLC demonstrated resolution of three osseous lesions and a reduction in uptake in the remaining lesion. This patient also experienced grade 2 cytokine release syndrome consistent with T-cell activation and was dose reduced to 8 mcg/kg. This patient is the only patient treated thus far with high tumor PD-L1 expression who is also HLA-A*02/ CMV+ and hence appropriate for the antigen seeding mechanism of action. Antigen seeding and the alteration of tumor immunophenotype is a novel mechanism in immuno-oncology unique to the ETB scaffold.
- Treatment-related AEs including immune-related AEs have been largely restricted to grade 1-2. The 63 mcg/kg dose was well-tolerated and dose escalation continues at 83 mcg/kg.
- Two Phase I dose expansion cohorts are planned for 2023 including for patients with high PD-L1 tumor expression and for patients with low PD-L1 tumor expression.

**MT-8421 (CTLA-4 ETB)**

- MT-8421 was designed to target CTLA-4 in a wholly distinct manner from the current monoclonal antibody approaches. MT-8421 was designed to eliminate CTLA-4-expressing Tregs in the TME through a direct cell-kill mechanism independent of the effector cell presence that antibodies rely upon.
- MT-8421 was also designed to avoid CTLA-4 blockade in the periphery, the major mechanism of antibody-mediated autoimmune toxicity.
- MTEM has received clearance by the United States Food and Drug Administration ("FDA") following review of its IND to proceed for clinical testing of its novel MT-8421 ETB program targeting CTLA-4 in patients with relapsed/refractory solid tumors previously exposed to checkpoint inhibitors.
- MTEM expects to initiate a first-in-human Phase I study with MT-8421 by mid-year 2023.

**MT-0169 (CD38 ETB)**

- MT-0169 was designed to destroy CD38+ tumor cells through internalization of CD38 and cell destruction via a novel mechanism of action (enzymatic ribosomal destruction and immunogenic cell death). Highlights from the on-going Phase I include:
    - The 5 mcg/kg cohort completed recruitment (N=4) and analysis with no related AEs higher than grade 1 and no cardiac AEs.
    - A VGPR was seen in a patient with extramedullary IgA myeloma treated at 5 mcg/kg. The patient had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative, and significant improvement of hemoglobin to normal values without transfusion. The patient's disease was quad-agent refractory including CD38-targeting, proteosome inhibitor, IMiD, and a BCMA bispecific antibody. The patient's response improved to a stringent Complete Response and they remain on study.
    - Dose escalation completed with three patients enrolled at 10 mcg/kg and no related AE's higher than grade 2.
    - Dose escalation is now proceeding at 15 mcg/kg.

**Key Milestones for 2023**

- Accelerating enrollment across all clinical programs with advancement into later stage trials expected in 2023
- Initiation of first-in-human Phase I study for MT-8421
- Advancement of Bristol Myers Squibb research collaboration across multiple targets

**Conferences**

- MTEM participated in the Breast and Lung Cancer Panel at TD Cowen 43rd Annual Health Care Conference, which took place in Boston, Tuesday, March 7, 2023, 10:30am – 11:30am ET. The webcast can be accessed here and in the "News and Media" section of the corporate website.
- MTEM presented a fireside chat at the virtual Oppenheimer 33rd Annual Healthcare Conference, which took place Wednesday, March 15, 2023, 12:40am ET. The webcast can be accessed here and in the "News and Media" section of the corporate website.
- MTEM will present an abstract, "Engineered Toxin Bodies (ETBs): Clinical stage immunotoxins with a safer and differentiated profile", Monday, April 17, 2023, 1:30pm – 5pm ET (Section 13, Poster Board No 29, No. 2661), at the American Association for Cancer Research ("AACR") Annual Meeting taking place at the Orange County Convention Center in Orlando, FL from April 14 – 19, 2023.

**Financial Results**

The net loss attributable to common shareholders for the fourth quarter of 2022 was $22.0 million, or $0.39 per basic and diluted share. This compares with a net loss attributable to common shareholders of $10.2 million, or $0.18 per basic and diluted share, for the same period in 2021.

Revenues for the fourth quarter of 2022 were $2.6 million, compared to $18.0 million for the same period in 2021. Revenues for the fourth quarter of 2022 were comprised of revenues from collaborative research and development agreements with Bristol Myers Squibb.

Total research and development expenses for the fourth quarter of 2022 were $17.6 million, compared with $19.3 million for the same period in 2021. Total general and administrative expenses for the fourth quarter of 2022 were $6.1 million, compared with $7.9 million for the same period in 2021.

As of December 31, 2022, MTEM's cash and investments totaled $61.0 million, including borrowings of $35.0 million under its K2 Loan and Security Agreement whose scheduled maturity date for repayment is June 1, 2024, subject to continued compliance with the financial covenant and solvency requirements therein. MTEM is currently in compliance with such covenant and requirements, and expects to continue to be in compliance into the fourth quarter of 2023. Any default of the financial covenant or solvency requirements would potentially trigger accelerated repayment. Subject to MTEM's continued compliance with the K2 Loan and Security Agreement, MTEM anticipates a cash runway into the second quarter of 2024.

**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.

**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 Company's continued compliance with the financial covenant and solvency requirements in the K2 Loan and Security Agreement, the Company's cash runway, the safety or potential efficacy of Molecular Templates' drug or biologic candidates; Molecular Templates' belief that its proprietary biologic drug platform technology, or ETBs, provides for a differentiated mechanism of action for cancer; and the prospects for continued clinical development and regulatory approval. 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 following: whether the Company can realize the anticipated cost-savings of its restructuring, whether the Company is successful at raising additional capital, whether beyond 2023 the Company is able to negotiate an amendment to the financial covenant or solvency requirements or otherwise amend the K2 Loan and Security Agreement (to the extent needed), the uncertainties inherent in the preclinical and clinical development process, including the fact that interim results may not be indicative of future results;*

*Molecular Templates' ability to timely enroll patients in its clinical trials; the ability of Molecular Templates' to protect its intellectual property rights; 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, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development revenue, related party | $ — | $ — | $ — | $ 13,136 |
| Research and development revenue, other | 2,611 | 17,964 | 19,754 | 25,561 |
| Total revenue | 2,611 | 17,964 | 19,754 | 38,697 |
| Operating expenses: | | | | |
| Research and development | 17,590 | 19,337 | 82,425 | 84,665 |
| General and administrative | 6,080 | 7,928 | 26,200 | 34,106 |
| Total operating expenses | 23,670 | 27,265 | 108,625 | 118,771 |
| Loss from operations | 21,059 | 9,301 | 88,871 | 80,074 |
| Interest and other income, net | 425 | 126 | 988 | 434 |
| Interest and other expense, net | (1,388) | (1,068) | (4,782) | (3,369) |
| Loss before provision for income taxes | 22,022 | 10,243 | 92,665 | 83,009 |
| Provision for income taxes | 27 | — | 53 | — |
| Net loss attributable to common shareholders | $ 22,049 | $ 10,243 | $ 92,718 | $ 83,009 |
| Net loss per share attributable to common shareholders: | | | | |
| Basic and diluted | $ 0.39 | $ 0.18 | $ 1.65 | $ 1.50 |
| Weighted average number of shares used in net loss per share calculations: | | | | |
| Basic and diluted | 56,351,647 | 56,305,049 | 56,334,456 | 55,297,798 |

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 32,190 | $ 24,983 |
| Marketable securities, current | 28,859 | 118,061 |
| Prepaid expenses | 3,459 | 3,917 |
| Other current assets | 3,790 | 1,254 |
| Total current assets | 68,298 | 148,215 |
| Marketable securities, non-current | — | 8,986 |
| Operating lease right-of-use assets | 11,132 | 8,608 |
| Property and equipment, net | 14,632 | 19,309 |
| Other assets | 3,486 | 7,244 |
| Total assets | $ 97,548 | $ 192,362 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 504 | $ 1,612 |
| Accrued liabilities | 8,823 | 9,515 |
| Deferred revenue, current | 45,573 | 32,937 |
| Other current liabilities | 2,182 | 2,606 |
| Total current liabilities | 57,082 | 46,670 |
| Deferred revenue, long-term | 5,904 | 33,350 |
| Long-term debt, net of current portion | 36,168 | 35,491 |
| Operating lease liabilities | 12,231 | 9,564 |
| Other liabilities | 1,295 | 1,625 |
| Total liabilities | 112,680 | 126,700 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity | | |
| Preferred stock, $0.001 par value: | | |
| Authorized: 2,000,000 shares at December 31, 2022 and December 31, 2021; issued and outstanding: 250 shares at December 31, 2022 and December 31, 2021 | — | — |
| Common stock, $0.001 par value: | | |
| Authorized: 150,000,000 shares at December 31, 2022 and December 31, 2021; issued and outstanding: 56,351,647 December 31, 2022 and 56,305,049 shares at December 31, 2021 | 56 | 56 |
| Additional paid-in capital | 429,646 | 417,704 |
| Accumulated other comprehensive loss | (66) | (48) |
| Accumulated deficit | (444,768) | (352,050) |
| Total stockholders' (deficit) equity | (15,132) | 65,662 |
| Total liabilities and stockholders' (deficit) equity | $ 97,548 | $ 192,362 |

Source: Molecular Templates, Inc.