

Molecular Templates, Inc. Reports Second Quarter 2023 Financial Results and Business Update

AUSTIN, Texas, Aug. 10, 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 and business updates for the second quarter of 2023.

Eric Poma, PhD., Chief Executive and Chief Scientific Officer of MTEM, stated, "ETBs represent a novel approach to the treatment of cancer with differentiated biology and unique mechanisms of action. We expect to see substantial data across all three of our clinical programs with updates throughout this year and into 2024."

Company Highlights

- Up to \$40 million Private Placement entered with existing and new investors to fund clinical development of MT-6402, MT-8421, and MT-0169
- Outstanding debt fully discharged and satisfied in Restructuring Agreement with K2 Health Ventures LLC
- MT-0169 screening and enrollment resumed following removal of partial clinical hold on patient enrollment by U.S. Food and Drug Administration
- First-in-human phase I study for MT-8421 targeting CTLA-4-expressing regulatory T-cells ("Tregs") in the tumor microenvironment ("TME") for elimination without affecting Tregs in the periphery to begin in 3Q 2023
- Clinical data for each program continues to demonstrate 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
- No instances of capillary leak syndrome or other manifestations of innate immunity have been observed to date with any next-generation ETB
- Focus on preclinical activities related to Bristol Myers Squibb collaboration moves forward

July 2023 Private Placement

On July 12, 2023, and as described in Note 14 "Subsequent Events" of the financial statements included in Item 1 of the Quarterly Report on Form 10-Q, we entered into the July 2023 Purchase Agreement which provides for the private placement of shares of our

common stock and warrants to purchase shares of our common stock in two tranches. The initial tranche of the July 2023 Private Placement closed on July 17, 2023, and consisted of the issuance of (i) 24,260,644 shares of our common stock at a price of \$0.47 per share (the closing price per share of our common stock as reported by the Nasdaq Capital Market on July 12, 2023), and (ii) July 2023 Pre-Funded Warrants exercisable for up to 18,331,547 shares of our common stock. The price of the July 2023 Pre-Funded Warrants was \$0.469 per underlying share of our common stock. We received approximately \$20 million in gross proceeds in connection with the closing of the initial tranche and net proceeds, following the payment of related offering expenses, of approximately \$18.7 million. The second tranche would include gross proceeds of approximately \$20 million and would consist of the sale and issuance of an additional 42.6 million shares of common stock (or pre-funded warrants in lieu thereof) on the same pricing terms, and would close if certain conditions were met within the 12 month period described in the July 2023 Purchase Agreement, including requirements that shares of our common stock trade for a 10-day volume weighted average price of at least \$1.41 per share with aggregate trading volume during the same 10-day period of at least 10 million shares. In addition, upon this second tranche closing, we would issue to the July 2023 Purchasers Second Closing Warrants representing the right to purchase an additional 85.2 million shares of our common stock at an exercise price of \$0.47 per share, in exchange for the payment of \$0.125 per underlying share of stock. In the aggregate, these Second Closing Warrants would represent 100% warrant coverage of the number of shares of common stock (or pre-funded warrants) sold in the initial and second tranche, and it would have a term of five years. We intend to use the net proceeds from the July 2023 Private Placement to fund our ongoing clinical studies, working capital and for general corporate purposes and to continue our collaboration activities with BMS.

Restructuring Agreement with K2 HealthVentures LLC("K2HV")

On June 16, 2023 and as described in Note 8 "Borrowing Arrangements and Debt Extinguishment" in our financial statements included in Item 1 of the Quarterly Report on Form 10-Q, we entered into the Convertible Secured Contingent Value Right Agreement (the "CVR Agreement") with K2HV to fully satisfy and discharge our outstanding secured debt obligations and terminate all other obligations under the existing debt financing facility between us and K2HV in exchange for an aggregate repayment in cash of \$27.5 million, the granting of a contingent value right to K2HV and the issuance of a warrant to purchase shares of our common stock to K2HV's affiliated holder. These contingent value rights require payments to K2HV upon the occurrence of certain events or Acceleration Events described in the CVR Agreement, and payments due for these events is initially capped at \$10.3 million which, if not repaid, is subject to various escalating multipliers, as further described in the CVR Agreement. In addition, upon a Change in Control, as defined in the CVR Agreement, we are required to pay an additional payment of \$2.5 million. In lieu of a portion of these contingent value rights, K2HV may convert up to \$3,000,000 of the Remaining Value, as defined in the CVR Agreement, into an aggregate of 6,124,011 shares of our common stock, subject to adjustment for any stock splits and similar events so long as the number of shares of common stock underlying such conversion right, together with the shares of common stock underlying the warrant, do not exceed 19.99% of the number of shares of our common stock outstanding immediate prior to the execution of the CVR Agreement. In satisfaction of our obligations to issue the warrant to K2HV's affiliate pursuant to the CVR Agreement, we issued a warrant to purchase up to 5,103,343 shares of our common stock at an exercise price of \$0.3919 per share. This warrant has a term of 10 years. To protect its interest in any potential payment of the Remaining Value, K2HV has a security interest in, subject to certain limited exceptions, all assets (including intellectual property) of the Company. Further and pursuant to the terms of the CVR Agreement, we may not (i) incur any indebtedness for borrowed money that is structured as senior or pari passu to K2HV's outstanding payments without K2HV's consent or (ii) permit any other liens (other than customary permitted liens) on this collateral without K2HV's consent.

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).
- On June 1, 2023, we announced that the U.S. Food and Drug Administration (the "FDA"), after reviewing safety data on the program, removed the partial clinical hold (placed April 2023) on patient enrollment for our MT-0169 trial effective as of May 31, 2023.
 - In April 2023, the FDA placed the Phase I study for MT-0169 on a partial clinical hold based on previously disclosed cardiac AEs noted in two patients dosed at 50 mcg/kg that prompted the dose reduction to 5 mcg/kg last year. Under the partial clinical hold, current study participants could continue treatment, but no new patients were to be enrolled until the partial hold was lifted by the FDA. We submitted our response to the partial clinical hold to the FDA in May 2023, and the partial clinical hold was lifted by the FDA on May 31, 2023.
- Screening and enrollment have resumed for cohort 3 at 15 mcg/kg following a review of the safety data from cohorts 1 (5 mcg/kg) and 2 (10 mcg/kg) in which no cardiac AEs were observed.
- Of the patients treated, one patient with extramedullary IgA myeloma treated at 5 mcg/kg has had a marked reduction in IgA serum protein, conversion from immunofixation positive to negative and resolution of uptake on bone scan of skeletal lesions demonstrating a stringent Complete Response ("CR").
 - The patient's disease was quad-agent refractory including CD38-targeting antibody, proteosome inhibitor, IMiD, and a BCMA bispecific antibody.
 - The patient continues on study in a stringent CR at cycle 12.

MT-8421 (CTLA-4 ETB)

- MT-8421, along with MT-6402, represent our unique approach to immuno-oncology based on dismantling the TME through direct cell-kill of tumor and immune cells and not only the blocking of ligand-ligand interactions seen with current antibody therapeutics.
- The ETB approach includes potent destruction of CTLA4+ regulatory T cells ("Tregs") via enzymatic ribosome destruction, and the mechanism of cell kill is independent of TME.
- MT-8421 preferentially destroys high CTLA4 expressing Tregs in the TME relative to peripheral Tregs which are lower CTLA4 expressing.
- Clinical sites are open, and we expect the first patient to be enrolled in this Phase 1 study in 3Q 2023.

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 pretreated checkpoint therapy experienced patients.
- Dose escalation in the Phase I study continues as planned for 2023, with one expansion for patients with high PD-L1 tumor expression (≥ 50%) and the other expansion for patients with low (1-49%) PD-L1 tumor expression.
- As of June 2023, patients have been treated across seven dose escalation cohorts of 16 mcg/kg, 24 mcg/kg, 32 mcg/kg, 42 mcg/kg, 63 mcg/kg, 83 mcg/kg, and 100 mcg/kg in the MT-6402 study of patients with relapsed/refractory tumors that express PD-L1. We continue to observe pharmacodynamic ("PD") effects including the depletion of PD-L1+ monocytes, MDSCs, PD-L1+ dendritic cells, as well as T cell activation.
- One patient with high tumor PD-L1 expression who also had Antigen Seeding capability, demonstrated tumor regression while being dosed with MT-6402 for over 7 months.
 - This patient, with NSCLC, was treated in cohort 1 (16 mcg/kg) and demonstrated resolution of three osseous lesions and a reduction in uptake in the remaining lesion.
 - This patient also experienced grade 2 cytokine release syndrome ("CRS") consistent with T-cell activation and was dose reduced to 8 mcg/kg.
 - This patient had evaluable-only multiple sites of bone disease that appeared to have resolved on bone scan after 3 – 4 months on MT-6402 with only one remaining site which showed decreased uptake.
- One patient in cohort 5 (63 mcg/kg) with metastatic squamous cell nasopharynx carcinoma with disease progression after radiation therapy, chemotherapy, and pembrolizumab had a Partial Response ("PR") (RECIST) with a 63% reduction in the index lesion after cycle 2.
 - The PR was confirmed after cycle 4 with a 71% reduction and the patient remains on treatment and in a response in cycle 10.
 - This patient's tumor had 2% PD-L1 expression and was not HLA-A*02, suggesting the response is due to T-cell activation through the clearance of PD-L1+ immune cells. The patient showed a >250% increase in CD8/CD4 T-cell ratios.
 - To date, treatment-related AEs including immune related AEs have been largely restricted to grade 1 or grade 2.

Research and Collaboration

MTEM continues to expand and develop its unique approach to immuno-oncology targets in collaboration with Bristol Myers Squibb.

Key Milestones for 2023

Accelerating enrollment across all clinical programs

- Initiation of first-in-human Phase I study for MT-8421 in 3Q 2023
- Advancement of Bristol Myers Squibb research collaboration across multiple targets
- MTEM expects to provide periodic updates on MT-6402, MT-8421, and MT-0169 throughout 2023.

Upcoming Conferences

MTEM will make a virtual presentation 7:00am Monday, September 11, 2023, at the H.C. Wainwright 25th Annual Global Conference taking place at the Lotte Palace Hotel in New York, NY from September 11 - 13, 2023. The presentation will be accessible via the corporate website. One-on-one meetings may be scheduled via H.C. Wainwright representative or by directly contacting Molecular Templates.

Financial Results

The net loss attributable to common shareholders for the second quarter of 2023 was \$10.9 million, or \$0.19 per basic share and per diluted share. This compares with a net loss attributable to common shareholders of \$24.4 million, or \$0.43 per basic and diluted share, for the same period in 2022.

Revenues for the second quarter of 2023 were \$6.9 million, compared to \$4.4 million for the same period in 2022. Revenues for the second quarter of 2023 were comprised of revenues from collaborative research and development agreements with Bristol Myers Squibb and grant revenue from CPRIT.

Total research and development expenses for the second quarter of 2023 were \$13.4 million, compared with \$21.4 million for the same period in 2022. Total general and administrative expenses for the second quarter of 2023 were \$5.2 million, compared with \$6.6 million for the same period in 2022.

As of June 30, 2023, MTEM's cash and cash equivalents totaled \$5.0 million. Based on the MTEM's cash and cash equivalents, the proceeds from the first tranche of the July 2023 private placement described above, the anticipated cost-savings from internal restructuring related activities, and other assumptions, management anticipates that MTEM will be able to fund its planned operating expenses and capital expenditure requirements to the third quarter 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, including, but not limited to those regarding strategy, future operations, the Company's ability to execute on its objectives, prospects, plans, and future execution of corporate goals. 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. 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: the continued availability of financing on commercially reasonable terms, whether Molecular Templates' cash resources will be sufficient to fund its continuing operations; the results of MTEM's ongoing clinical studies and its collaboration activities with BMS, the ability to effectively operate MTEM, and those risks identified under the heading "Risk Factors" in Molecular Templates' filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and any subsequent reports filed with the Securities and Exchange Commission. 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,				
		2023		2022		2023		2022
Research and development revenue	\$	6,627	\$	4,417	\$	40,254	\$	12,903
Grant revenue		238		_		3,240		_
Total revenue		6,865		4,417		43,494		12,903
Operating expenses:								
Research and development		13,413		21,365		32,455		42,862
General and administrative		5,195		6,566		10,997		14,186
Total operating expenses		18,608		27,931		43,452		57,048
Income/(loss) from operations		(11,743)		(23,514)		42		(44,145)
Interest and other income, net		365		186		820		256
Interest and other expense, net		(1,189)		(1,092)		(2,584)		(2,141)
Gain on extinguishment of debt		1,795		_		1,795		_
Change in valuation of contingent value right		303		_		303		
Loss on disposal of property and equipment		(399)		_		(399)		(1)
Net loss attributable to common shareholders	\$	(10,868)	\$	(24,420)	\$	(23)	\$	(46,031)
Net loss per share attributable to common shareholders:								
Basic and diluted	\$	(0.19)	\$	(0.43)	\$	0.00	\$	(0.82)
Weighted average number of shares used in net loss per share calculations:								
Basic and diluted		56,351,647		56,329,585		56,351,647		56,317,384

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

	June 30, 2023 (unaudited)		December 31, 2022		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	4,952	\$	32,190	
Marketable securities, current		_		28,859	
Prepaid expenses		3,887		3,459	
Grants revenue receivable		274		_	
Other current assets		2,710		3,790	
Total current assets		11,823		68,298	
Operating lease right-of-use assets		10,163		11,132	
Property and equipment, net		10,158		14,632	
Other assets		3,368		3,486	
Total assets	\$	35,512	\$	97,548	
LIABILITIES AND STOCKHOLDERS' DEFICIT Current liabilities:					
Accounts payable	\$	4,669	\$	504	
Accrued liabilities		3,510		8,823	
Deferred revenue, current		16,409		45,573	
Other current liabilities		2,349		2,182	
Total current liabilities	-	26,937		57,082	
Deferred revenue, long-term		19		5,904	
Long-term debt, net of current portion		_		36,168	
Operating lease liabilities, long term portion		11,029		12,231	
Contingent value right liability		4,856		_	
Other liabilities		1,349		1,295	
Total liabilities		44,190		112,680	
Commitments and contingencies					
Stockholders' deficit					
Preferred stock, \$0.001 par value:					
Authorized: 2,000,000 shares as of June 30, 2023 and December 31, 2022; issued and outstanding: 250 shares at June 30, 2023 and December 31, 2022		_		_	
Common stock, \$0.001 par value:					
Authorized: 150,000,000 shares as of June 30, 2023 and December 31, 2022; issued and outstanding: 56,351,647 shares at June 30, 2023 and December 31, 2022		56		56	
Additional paid-in capital		436,056		429,646	
Accumulated other comprehensive income/(loss)		1		(66)	
Accumulated deficit		(444,791)		(444,768)	
Total stockholders' deficit		(8,678)		(15,132)	
Total liabilities and stockholders' deficit	\$	35,512	\$	97,548	
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Source: Molecular Templates, Inc.