

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

AUSTIN, Texas, Nov. 13, 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 third quarter of 2023.

Eric Poma, PhD., Chief Executive and Chief Scientific Officer of MTEM, stated, "ETBs represent a new approach to oncology drug development that continue to show unique biology and monotherapy activity in heavily pre-treated patients. We expect to see substantial additional data across all three of our clinical programs with updates throughout this year and into 2024."

Company Highlights

- Initiation of expansion study with MT-6402 (PD-L1) exploring 63 and 83 mcg/kg doses; compelling early evidence of monotherapy activity in patients with relapsed or refractory Head and Neck cancer observed at the 63 and 83 mcg/kg doses observed
- First patient dosed in phase I study for MT-8421 targeting CTLA-4-expressing regulatory T-cells ("Tregs") in the tumor microenvironment ("TME") for elimination without affecting peripheral Tregs
- MT-0169 (CD38): The company is in the process of declaring the recommended doses that will be further investigated in CD38+ malignancies.
- 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 observed
- No instances of capillary leak syndrome ("CLS") 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

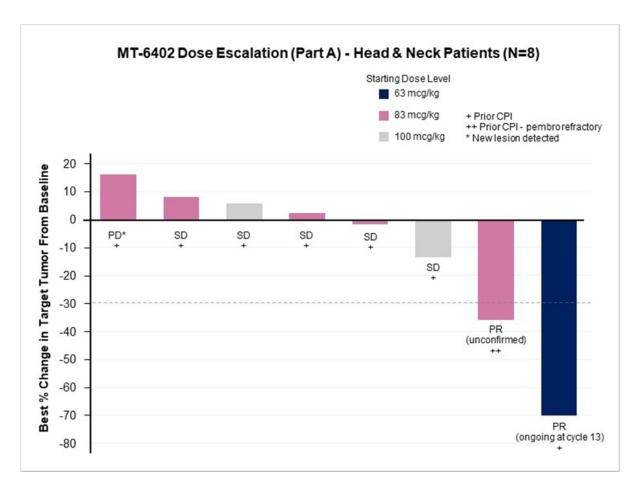
MT-6402 (PD-L1 ETB)

The Part A dose escalation of the phase I for MT-6402 has been completed with no Grade 4 or Grade 5 drug-related adverse events having been observed to date.

In the Part A dose escalation, 10 patients with head and neck cancer were treated at doses of 63, 83, or 100 mcg/kg. Two of these patients were not evaluable for the cycle 1 dose-limiting toxicity ("DLT") period because of early progression and came off study after receiving only one or two doses of MT-6402, respectively. Of the remaining eight head and neck cancer patients, the best responses observed were as follows: two had a partial response (one unconfirmed), and a third patient had evidence of tumor regression. All three patients had progressed after multiple lines of treatment including checkpoint therapy. The unconfirmed partial response was in a patient who was pembrolizumab-refractory.

Three other patients had stable disease of 6, 4, and 2 months, respectively, before disease progression or discontinuation. A fourth patient remains in stable disease at cycle 5. One patient progressed at the end of cycle 2. Of these 8 patients, only one patient (the patient with stable disease through 6 cycles) had a PD-L1 tumor proportion score ("TPS") greater than 50%.

"We are very excited to see responses in heavily pre-treated, checkpoint-experienced, head and neck cancer patients, a setting with high unmet medical need," said Eric Poma. "The TME in head and neck tumors is typically rich with immunosuppressive cells, but current checkpoint monotherapy in I/O-naïve head and neck patients has a ~15% response rate. Here, in patients who have progressed on checkpoint therapy, we believe we are seeing evidence of monotherapy activity of long duration and monotherapy activity in a patient refractory to checkpoint therapy. The responses observed to date were in patients with CPS <20% and showed concomitant increases in cytokines associated with T-cell activation that are not seen with other checkpoint therapies. We believe these data demonstrate a new and potentially best-in-class approach to targeting the PD-1-PD-L1 axis."



"MT-6402 appears generally well-tolerated at the 63 and 83 mcg/kg doses with no Grade 4 or Grade 5 adverse events and no instances of CLS seen at any dose," said Dr. Maurizio Voi, Chief Medical Officer of Molecular Templates. "The irAE profile of MT-6402 appears to be consistent with that seen with other checkpoint therapies."

The Part B dose expansion is ongoing, with three patients currently on treatment but not yet evaluable for efficacy. The 63 and 83 mcg/kg doses will be studied in the expansion cohort in patients with >50% tumor expression of PD-L1, allowing for the potential of direct tumor cell-kill. Additionally, in patients with the HLA-A*02 haplotype and who are CMV+, the antigen seeding mechanism of MT-6402 may be engaged.

MT-8421 (CTLA-4 ETB)

- MT-8421, along with MT-6402, represent our unique approach to immuno-oncology based on dismantling the TME through, and the elimination of, immunosuppressive cells in the TME.
- MT-8421 is designed to potently destroy CTLA4+ Tregs via enzymatic ribosome destruction but does not have activity against low CTLA-4 expressing peripheral Tregs.
- Clinical sites are open and enrollment has commenced on this program.

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).

- MT-0169 will continue to be studied in CD38 hematological malignancies. No adverse events ≥ Grade 3 have been observed.
- One patient with extra medullary 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.
 - 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 response at cycle 16.

Research and Collaboration

 MTEM continues to make progress in the drug discovery collaboration with Bristol Myers Squibb.

Key Upcoming Milestones

- Accelerating enrollment across all clinical programs.
- Advancement of Bristol Myers Squibb research collaboration across multiple targets. Under terms of the agreement, Molecular Templates received \$70M upfront and will undertake research responsibilities for the discovery of next-generation ETBs for multiple undisclosed targets.
- MTEM expects to provide a year-end update and periodic updates on MT-6402, MT-8421, and MT-0169 throughout 2024.

Upcoming Conferences

Stifel Annual Health Care Conference

- Format: Live Presentation and One-on-One Meetings
- Date: Wednesday, November 15, 2023
- Time: 10:55 am Eastern Time
- Location: Lotte New York Palace Hotel, New York, NY
- Webcast: The live-streamed webcast can be accessed here
- Meetings: To be scheduled by contact with Stifel representative

The presentation link will be archived for 90 days here in the "News and Media" section of the corporate website.

Evercore ISI 6th Annual HealthCONx Conference

Format: One-on-one meetings

Dates: November 28 - 30, 2023

• Location: Kimpton Epic Hotel, Miami, FL

• Meetings: To be scheduled directly with Molecular Templates

Financial Results

The net loss attributable to common shareholders for the third quarter of 2023 was \$4.2 million, or \$0.82 per basic share and per diluted share. This compares with a net loss attributable to common shareholders of \$24.6 million, or \$6.56 per basic and diluted share, for the same period in 2022.

Revenues for the third quarter of 2023 were \$6.8 million, compared to \$4.2 million for the same period in 2022. Revenues for the third quarter of 2023 were comprised of revenues from the collaborative research and development agreement with Bristol Myers Squibb and grant revenue from CPRIT.

Total research and development expenses for the third quarter of 2023 were \$7.6 million, compared with \$22.0 million for the same period in 2022. Total general and administrative expenses for the third quarter of 2023 were \$4.3 million, compared with \$5.9 million for the same period in 2022.

As of September 30, 2023, MTEM's cash and cash equivalents totaled \$15.8 million. MTEM anticipates cash runway to the end of 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, including, but not limited to those regarding strategy, future operations, the Company's ability to execute on its objectives, prospects, plans, future clinical development of the Company's product candidates, any implication that the preliminary results or the results of earlier clinical trials will be representative of the results of future clinical trials, the potential benefits, safety or efficacy and any evaluations or judgements regarding the Company's product candidates, 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 (the "SEC"), including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and any subsequent reports filed 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 September 30,			Nine Months Ended September 30,				
		2023		2022		2023		2022
Research and development revenue	\$	5,732	\$	4,240	\$	45,986	\$	17,143
Grant revenue		1,064		_		4,304		_
Total revenue		6,796		4,240		50,290		17,143
Operating expenses:								
Research and development		7,624		21,973		40,079		64,835
General and administrative		4,309		5,934		15,306		20,120
Total operating expenses		11,933		27,907		55,385		84,955
Loss from operations		5,137		23,667		5,095		67,812
Interest and other income, net		210		307		1,030		563
Interest and other expense, net		(31)		(1,224)		(2,615)		(3,365)
Gain on extinguishment of debt		_		_		1,795		_
Change in valuation of contingent value right		881		_		1,184		_
Loss on disposal of property and equipment		(76)		(28)		(475)		(29)
Loss before provision for income taxes		4,153		24,612		4,176		70,643
Provision for income taxes		_		26		_		26
Net loss attributable to common stockholders	\$	4,153	\$	24,638	\$	4,176	\$	70,669
Net loss per share attributable to common stockholders:								
Basic and diluted	\$	0.82	\$	6.56	\$	0.99	\$	18.82
Weighted average number of shares used in net loss per share calculations:								
Basic and diluted		5,092,859		3,756,658		4,206,986		3,755,178

Molecular Templates, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

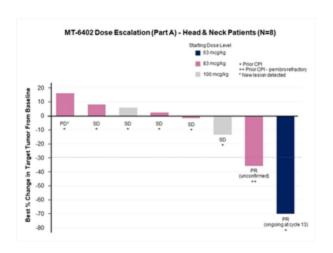
(in thousands, except share and per share data)

		ember 30, 2023 unaudited)	December 31, 2022		
ASSETS	-				
Current assets:					
Cash and cash equivalents	\$	15,811	\$	32,190	
Marketable securities, current		_		28,859	
Prepaid expenses		2,999		3,459	
Other current assets		3,890		3,790	
Total current assets		22,700		68,298	
Operating lease right-of-use assets		9,667		11,132	
Property and equipment, net		8,578		14,632	
Other assets		3,116		3,486	
Total assets	\$	44,061	\$	97,548	
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)					
Current liabilities:					
Accounts payable	\$	2,583	\$	504	
Accrued liabilities		3,303		8,823	
Deferred revenue, current		13,210		45,573	
Other current liabilities		2,416		2,182	
Total current liabilities		21,512		57,082	
Deferred revenue, long-term		_		5,904	
Long-term debt, net of current portion		_		36,168	
Operating lease liabilities, long term portion		10,396		12,231	
Contingent value right liability		3,975		_	
Other liabilities		1,377		1,295	
Total liabilities		37,260		112,680	
Commitments and contingencies					
Stockholders' equity/(deficit)					
Preferred stock, \$0.001 par value:					
Authorized: 2,000,000 shares as of September 30, 2023 and December 31,					
2022; Issued and outstanding: 250 shares at September 30, 2023 and					
December 31, 2022		_		_	
Common stock, \$0.001 par value:					
Authorized: 150,000,000 shares as of September 30, 2023 and December 31, 2022; Issued and outstanding: 5,374,268 shares at September 30, 2023 and					
3,756,711 shares at December 31, 2022 respectively1		5		4	
Additional paid-in capital1				•	
·		455,739 1		429,698	
Accumulated other comprehensive income/(loss) Accumulated deficit		(448,944)		(66) (444,768)	
Total stockholders' equity/(deficit)					
	Φ.	6,801	Φ.	(15,132)	
Total liabilities and stockholders' equity/(deficit)	\$	44,061	\$	97,548	

^{1.} Prior period amounts have been retrospectively adjusted for the 1-for-15 reverse stock split that was effective August 11, 2023.



Source: Molecular Templates, Inc.



Head & Neck Patients (N=8)