March 29, 2024

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

AUSTIN, Texas, March 29, 2024 (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, 2023.

Company Highlights

- Durable single agent activity observed with MT-6402, a PD-L1 targeting direct-cell kill agent, in heavily pre-treated patients with low PD-L1+ head and neck cancer who had progressed on multiple prior therapies including checkpoint and EGFR antibodies.
- Enrollment is on-going in the dose escalation study with MT-8421, a novel CTLA-4 targeting agent designed to potently deplete Tregs in the tumor environment. Unique pharmacodynamic effects demonstrating potent Treg clearance and IL-2 increases observed in patients.
- Recently completed $9.5 million private placement supports continued funding of clinical stage programs.

Eric Poma, PhD., Chief Executive and Chief Scientific Officer of MTEM, stated, "We are very excited to see objective responses in heavily pre-treated, checkpoint-experienced head and neck cancer patients, a setting with high unmet medical need, with MT-6402. We are seeing evidence of monotherapy activity of long duration and in patients refractory to checkpoint therapy through a novel mechanism of tumor microenvironment remodeling. We believe these data demonstrate a new and potentially best-in-class approach to targeting the PD-1-PD-L1 axis." Dr. Poma further added, "MT-8421 is currently in dose escalation as a novel direct cell-kill approach targeting CTLA-4 to potently deplete Tregs in the tumor microenvironment. Through the first dose cohort, we are already seeing promising and differentiate pharmacodynamic effects including dramatic Treg depletion in patients."

MT-6402 (PD-L1 ETB)

- MT-6402 was designed to activate T-cells through direct cell-kill of immunosuppressive PD-L1+ immune cells resulting in a remodeling of the tumor microenvironment.
- In addition, MT-6402 can deliver and induce the presentation of an MHC class I CMV antigen on tumor cells for pre-existing CD8 T-cell recognition and destruction in HLA-A*02/CMV+ patients with high PD-L1 expression on their tumors.

- Compelling signal of monotherapy activity with MT-6402 at higher doses in relapsed or refractory head and neck cancer (R-R HNSCC) with dose expansion study planned in low PD-L1+ R-R HNSCC patients.
    - 10 patients with R-R HNSCC in dose escalation
    - Patients dosed at 63, 83 (MTD), or 100 mcg/kg; median # of prior treatments of greater than 3
    - 2 patients currently in responses; 1 patient (63 mcg/kg) has a confirmed PR with 70% reduction in tumor volume at cycle 18 (1 cycle = 4 weeks)
    - 1 patient (83 mcg/kg) has an uPR(37% reduction) at cycle 8 w/ reductions of 3%, 9%, and 15% across three previous cycles; the patient is on therapy in cycle 9
    - 2 patients (one uPR and one 15% reduction) came off therapy for Gr1 hs-Trop elevation; guidelines now revised to allow patients to continue therapy despite advent of Gr1 hs-Trop elevation. In all instances, Gr1 hs-Trop elevations were asymptomatic and without evidence of cardiac changes. Similar troponin changes are observed in patients receiving checkpoint inhibitors.
    - No gr 4 or gr 5 drug-related toxicities were observed
    - Patients with responses/tumor reduction had low PD-L1
- Dose expansion is on-going in patients with high PD-L1+ tumors.

MT-8421 (CTLA-4 ETB)

- MT-8421, along with MT-6402, represents our unique approach to immuno-oncology based on remodeling the tumor microenvironment through the elimination of immunosuppressive cells and activation of CD8 T-cells.
- MT-8421 is designed to potently destroy CTLA-4+ Tregs via enzymatic ribosome destruction but does not have activity against low CTLA-4 expressing peripheral Tregs.
- Two of the three patients enrolled in the first cohort remain on study in cycle 5. Both patients show evidence of Treg clearance and T-cell activation. Enrollment is on-going in the second cohort of 48 mcg/kg for the phase I study of MT-8421.

MT-0169 (CD38 ETB)

- MT-0169 is 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).
- A phase 1 study in patients with relapsed or refractory multiple myeloma was closed on Dec 2023 due to slow patient enrollment in the wake of multiple new approvals in myeloma. This study enrolled 14 patients and no drug-related Grade 4 or 5 adverse events have been observed. One patient with IgA myeloma who was quad-refractory was treated at 5 mcg/kg and had a stringent Complete Response for 16 cycles (1 cycle = 4 weeks) before discontinuing treatment for progression of disease.
- MTEM is evaluating plans to initiate an investigator sponsored study to evaluate MT-0169 in relapsed or refractory CD38+ AML patients.

Second Closing of July 2023 Private Placement

On March 28, 2024, the Company and certain institutional and accredited investors (the

"March 2024 Purchasers") entered into an Amended and Restated July 2023 Purchase Agreement pursuant to which the Company will issue common stock, prefunded warrants, and common warrants with an aggregate purchase price of $9.5 million on amended and restated second tranche terms. The second tranche, as amended and restated, will consist of the sale and issuance of (i) 1,209,612 shares of the Company's common stock (and, in lieu thereof, prefunded warrants to purchase 2,460,559 shares of the Company's common stock (the "March 2024 Prefunded Warrants")) for a purchase price of $2.35 per share of the Company's common stock (the closing price of our common stock on March 27, 2024 as reported by the Nasdaq Capital Market) and $2.349 per March 2024 Prefunded Warrant, and (ii) common stock warrants (the "March 2024 Common Warrants") to purchase up to 7,340,342 shares of the Company's common stock (or March 2024 Prefunded Warrants in lieu thereof) at an exercise price of $2.35 per share of the Company's common stock underlying the March 2024 Common Warrants. The March 2024 Common Warrants will be sold at a price of $0.125 per underlying share of common stock and will have a term of five years. The March 2024 Prefunded Warrants will expire when fully exercised in accordance with their terms. The March 2024 Prefunded Warrants and March 2024 Common Warrants may not be exercised if the aggregate number of shares of our common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation (4.99%/9.99%/19.99%); provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%. The Amended and Restated July 2023 Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchasers and customary indemnification rights and obligations of the parties. The second tranche will include gross proceeds of approximately $9.5 million and net proceeds, following the payment of related offering expenses, of approximately $8.9 million.

Key Milestones for 2024

- Clinical data on MT-6402 expansion cohorts in low and high PD-L1+ HNSCC patients
- Clinical data from dose escalation study for MT-8421 Treg depleting agent in solid tumors

Bristol-Myers Squibb Collaboration Agreement

On March 13, 2024, Bristol-Myers Squibb notified the Company that following a corporate portfolio prioritization process, it does not intend to continue the research collaboration it entered into with the Company pursuant to the BMS Collaboration Agreement and would be terminating the BMS Collaboration Agreement in its entirety. The termination will be effective on June 13, 2024, or 90 days following the Company's receipt of Bristol-Myers Squibb's written notice of termination. MTEM plans to reduce costs related to the Collaboration Agreement.

Conferences

MTEM will present an abstract, "First-in-human, dose escalation and expansion study of MT-6402, a novel engineered toxin body (ETB) targeting PD-L1, in patients with PD-L1 expressing relapsed/refractory advanced solid tumors: Interim Data", Tuesday, April 9, 2024, 9am – 12:30pm ET (Section 48, Poster #19, Abstract #CT191), at the American Association for Cancer Research ("AACR") Annual Meeting taking place in San Diego, CA.

Financial Results

The net loss attributable to common shareholders for the fourth quarter of 2023 was $3.9 million, or $0.73 per basic and diluted share. This compares with a net loss attributable to common shareholders of $22.0 million, or $5.87 per basic and diluted share, for the same period in 2022.

Revenues for the fourth quarter of 2023 were $7.0 million, compared to $2.6 million for the same period in 2022. Revenues for the fourth quarter of 2023 were comprised of revenues from collaborative research and development agreements with Bristol-Myers Squibb and grant revenue.

Total research and development expenses for the fourth quarter of 2023 were $8.8 million, compared with $17.6 million for the same period in 2022. Total general and administrative expenses for the fourth quarter of 2023 were $3.6 million, compared with $6.1 million for the same period in 2022.

As of December 31, 2023, MTEM's unrestricted cash and cash equivalents totaled $11.5 million. MTEM anticipates a cash runway into the second quarter of 2024. Following the completion of the recent Second Closing of the July 2023 Private Placement, the Company anticipates that cash runway will extend to the end of the fourth quarter 2024.

For more details on MTEM's financial results for 2023, refer to Form 10-K filed with the SEC.

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,	
	2023	2022	2023	2022
Research and development revenue	$ 6,639	$ 2,611	$ 52,625	$ 19,754
Grant revenue	377	—	4,681	—
Total revenue	7,016	2,611	57,306	19,754
Operating expenses:				
Research and development	8,796	17,590	48,875	82,425
General and administrative	3,591	6,080	18,897	26,200
Total operating expenses	12,387	23,670	67,772	108,625
Loss from operations	5,371	21,059	10,466	88,871
Interest and other income, net	178	425	1,208	988
Interest and other expense, net	(39)	(1,351)	(2,654)	(4,716)
Gain on extinguishment of debt	—	—	1,795	—
Change in valuation of contingent value right	1,273	—	2,457	—
Loss on disposal of property and equipment	—	(37)	(475)	(66)
Loss before provision (benefit) for income taxes	3,959	22,022	8,135	92,665
Provision (benefit) for income taxes	(11)	27	(11)	53
Net loss attributable to common shareholders	$ 3,948	$ 22,049	$ 8,124	$ 92,718
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 0.73	$ 5.87	$ 1.80	$ 24.69
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	5,374,268	3,756,711	4,501,206	3,755,564

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,523	$ 32,190
Marketable securities, current	—	28,859
Prepaid expenses	2,195	3,459
Grants revenue receivable	250	—
Other current assets	2,804	3,790
Total current assets	16,772	68,298
Operating lease right-of-use assets	9,161	11,132
Property and equipment, net	7,393	14,632
Other assets	2,057	3,486
Total assets	$ 35,383	$ 97,548
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,523	$ 504
Accrued liabilities	4,279	8,823
Deferred revenue, current	9,031	45,573
Other current liabilities	2,488	2,182
Total current liabilities	17,321	57,082
Deferred revenue, long-term	—	5,904
Long-term debt, net of current portion	—	36,168
Operating lease liabilities, long term portion	9,742	12,231
Contingent value right liability	2,702	—
Other liabilities	1,406	1,295
Total liabilities	31,171	112,680
Commitments and contingencies		
Stockholders' equity/(deficit)		
Preferred stock, $0.001 par value per share:		
Authorized: 2,000,000 shares as of December 31, 2023 and 2022; Issued and outstanding: 250 shares as of December 31, 2023 and 2022	—	—
Common stock, $0.001 par value per share:		
Authorized: 150,000,000 shares as of December 31, 2023 and 2022; Issued and outstanding: 5,374,268 shares as of December 31, 2023 and 3,756,711 shares as of December 31, 2022[1]	5	4
Additional paid-in capital[1]	457,099	429,698
Accumulated other comprehensive loss	—	(66)
Accumulated deficit	(452,892)	(444,768)
Total stockholders' equity/(deficit)	4,212	(15,132)
Total liabilities and stockholders' equity/(deficit)	$ 35,383	$ 97,548

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

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, interim results, or the results of earlier clinical trials or ongoing clinical trials will be representative of the results of future or later clinical trials or final results, the potential benefits, safety or efficacy and any evaluations or judgements regarding the Company's product candidates, [the results of any strategic process which are inherently uncertain at the present time] and future execution of corporate goals. In addition, when or if used in this press release, the words "may," "could," "should," "continue", "anticipate," "potential", "believe," "estimate," "appears", "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 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 Form 10-K for the year ended December 31, 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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Source: Molecular Templates, Inc.