UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2023

Molecular Templates, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-32979**	**94-3409596**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

9301 Amberglen Blvd, Suite 100
Austin, Texas 78729
(Address of Principal Executive Offices) (Zip Code)

(512) 869-1555
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	MTEM	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2023, Molecular Templates, Inc. (the "Company") announced its financial results for the third quarter of 2023 ended September 30, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this current report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

99.1	Press Release dated November 13, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Molecular Templates, Inc.

Date: November 13, 2023

By: /s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.
Chief Executive Officer

EXHIBIT 99.1

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***

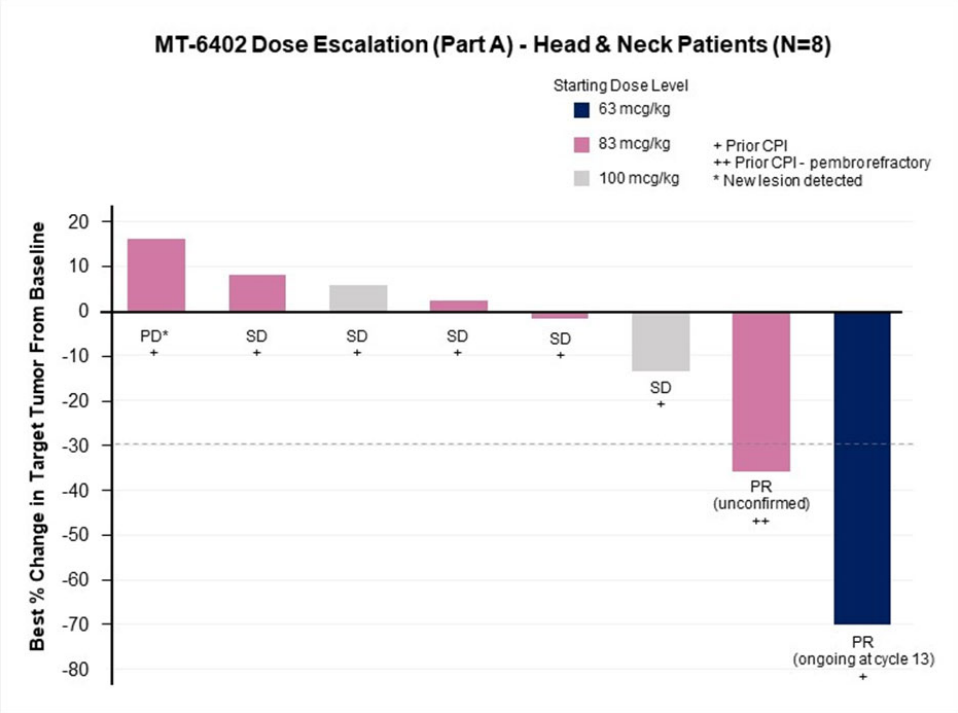
MT-6402 (PD-L1 ETB)

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)

	September 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 respectively[1]	5	4
Additional paid-in capital[1]	455,739	429,698
Accumulated other comprehensive income/(loss)	1	(66)
Accumulated deficit	(448,944)	(444,768)
Total stockholders' equity/(deficit)	6,801	(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.