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): May 15, 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 May 15, 2023, Molecular Templates, Inc. (the "Company") announced its financial results for the first quarter of 2023 ended March 31, 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 May 15, 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: May 15, 2023

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

EXHIBIT 99.1

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

Advancing clinical development of MT-6402, MT-8421, and MT-0169, and preclinical activities related to Bristol Myers Squibb collaboration

AUSTIN, Texas, May 15, 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 first quarter of 2023.

Eric Poma, PhD., Chief Executive and Chief Scientific Officer of MTEM, stated, "ETBs represent a novel platform with unique biology for the treatment of patients with disease that has progressed on available therapy. We continue to see an acceptable tolerability profile with these molecules and monotherapy activity."

Company Highlights

- 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.
- To date, no instances of capillary leak syndrome or other manifestations of innate immunity have been observed with any next-generation ETB.
- MT-6402 Phase I dose escalation continues at 100 mcg/kg. As of May 2023, patients with r/r tumors expressing PD-L1 have been treated across six dose escalation cohorts: 16 mcg/kg, 24 mcg/kg, 32 mcg/kg, 42 mcg/kg, 63 mcg/kg and 83 mcg/kg with clearance of immune cells in a PD-L1 targeted fashion and increases in cytokines associated with T-cell activation.
- A MT-6402 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 66% reduction, and the patient remains on treatment and in a response in cycle 7. This patient's tumor had 2% PD-L1 expression and the patient is 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.
- An IND for MT-8421 was accepted on March 8, 2023, with the first-in-human phase I study anticipated to begin by mid-year 2023. MT-8421 targets CTLA-4-expressing Tregs in the TME for elimination without affecting Tregs in the periphery.
- 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. Current study participants may continue treatment. MTEM has submitted its response to the partial hold to the FDA and anticipates feedback from the agency by the end of May. No cardiotoxicity was seen in patients treated at 5 mcg/kg or 10 mcg/kg; one patient treated at 5 mcg/kg remains in a stringent Complete Response at cycle 9.
- MTEM retains Stifel, Nicolaus & Company, Incorporated to assist in exploring strategic and financing alternatives.

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:
  - As of May 2023, patients have been treated across six dose escalation cohorts of 16 mcg/kg, 24 mcg/kg, 32 mcg/kg, 42 mcg/kg, 63 mcg/kg and 83 mcg/kg in the MT-6402 study of patients with relapsed/refractory tumors that express PD-L1. Dose escalation continues with patients being recruited at 100 mcg/kg.
  - 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 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 patient remains in a confirmed response at cycle 7.
  - Treatment-related AEs including immune-related AEs have been largely restricted to grade 1-2.
- 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 preferentially destroy high CTLA-4-expressing Tregs in the TME relative to peripheral Tregs which are lower CTLA-4 expressing, through an enzymatic ribosomal direct cell-kill mechanism independent of the TME.
- MT-8421 was also designed to avoid CTLA-4 blockade in the periphery, the major mechanism of antibody-mediated autoimmune toxicity.

- The IND for MT-8421 was filed in February 2023 and accepted in March 2023.
- The first-in-human Phase 1 study is expected to start by mid-year 2023.
- MT-8421 and MT-6402 represent a unique approach to immuno-oncology based on dismantling the TME through direct cell-kill of tumor and immune cells.

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).
- 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. MTEM has submitted its response to the partial hold to the FDA and anticipates feedback from the agency by the end of May.
- A stringent Complete Response 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 resolution of uptake on bone scan of skeletal lesions. The patient's disease was quad-agent refractory including CD38-targeting, proteosome inhibitor, IMiD, and a BCMA bispecific antibody. The patient continues on study in Cycle 9.

Research and Collaboration

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

Key Milestones for 2023

- Accelerating enrollment across clinical programs
- Initiation of first-in-human Phase I study for MT-8421 mid-year
- 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.

Conferences

- MTEM presented 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 which took place at the Orange County Convention Center in Orlando, FL from April 14 – 19, 2023. The abstract is visible in the presentations section of the corporate website.
- MTEM will present a poster on updated clinical data on MT-6402 (ETB targeting PD-L1), June 3, 2023, at the 2023 American Society for Clinical Oncology (ASCO) Annual Meeting taking place at McCormick Place in Chicago, Illinois and virtually from June 2 – 6, 2023. The poster will be visible in the presentations section of the corporate website. One-on-one meetings may be scheduled by directly contacting Molecular Templates.
- MTEM will participate at the BIO International conference taking place at the Boston Convention and Exhibition Center in Boston, MA from June 5 – 8, 2023. One-on-one meetings may be scheduled by directly contacting Molecular Templates.
- MTEM will present a virtual fireside chat Wednesday, June 7, 2023, at the Jefferies Healthcare Conference taking place at the Marriott Marquis in New York, NY from June 7 – 9, 2023. The presentation will be accessible via the corporate website. One-on-one meetings may be scheduled by directly contacting Molecular Templates.

Financial Results

The net income attributable to common shareholders for the first quarter of 2023 was $10.8 million, or $0.19 per basic and diluted share. This compares with a net loss attributable to common shareholders of ($21.6) million, or ($0.38) per basic and diluted share, for the same period in 2022.

Revenues for the first quarter of 2023 were $36.6 million, compared to $8.5 million for the same period in 2022. Revenues for the first 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 first quarter of 2023 were $19.0 million, compared with $21.5 million for the same period in 2022. Total general and administrative expenses for the first quarter of 2023 were $5.8 million, compared with $7.6 million for the same period in 2022.

On March 29, 2023, we implemented a strategic reprioritization and corresponding reduction in workforce, designed to focus on the clinical development programs for MT-6402, MT-8421 and MT-0169, and preclinical activities related to our collaboration with Bristol Myers Squibb Company ("Bristol Myers Squibb") (the "Restructuring"). The Restructuring reduced our current workforce by approximately 50%, resulted in the cessation of our MT-5111 clinical development program, and focused the majority of our pre-clinical efforts around activities related to the Bristol Myers Squibb collaboration. We incurred approximately $0.3 million in expenses related to the Restructuring in the first quarter of 2023 and estimate that we will incur an aggregate of approximately $0.4 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. We expect the remaining costs associated with the Restructuring to be incurred during the second quarter of 2023.

As of March 31, 2023, MTEM's cash and investments totaled $41.7 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 with the financial covenant and the solvency requirements late into the third 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 first quarter of 2024.

Process to Explore Strategic Alternatives

MTEM has an ongoing process to explore a range of strategic and financing alternatives to maximize shareholder value. In addition to continuing to explore any available financing alternatives to maintain continued compliance with the covenants and restrictions under the K2 Loan and Security Agreement as described above and to lengthen its cash runway, MTEM's process will also focus on identifying and evaluating any other strategic alternatives, including potentially the sale of all, or part, of the Company, or a merger. MTEM has retained the investment bank Stifel, Nicolaus & Company, Incorporated to act as a strategic advisor for this process. There can be no assurance that this strategic review process will result in the completion of any transaction. MTEM has not set a timetable for completion of this strategic review process.

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 Molecular Templates' continued compliance with the financial covenant and solvency requirements in the K2 Loan and Security Agreement; Molecular Templates' cash runway and continued operations; and the future possibility of a strategic transaction or financing alternative to maintain continued compliance with the covenants and restrictions in the K2 Loan and Security Agreement; 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 Molecular Templates can realize the anticipated cost-savings of its restructuring; whether Molecular Templates is successful at raising additional capital; whether beyond the third quarter of 2023, Molecular Templates 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.

Contacts:
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Molecular Templates, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Research and development revenue	$ 33,627	$ 8,486
Grant revenue	3,002	—
Total revenue	36,629	8,486
Operating expenses:		
Research and development	19,042	21,497

General and administrative	5,802	7,620
Total operating expenses	24,844	29,117
Income/(loss) from operations	11,785	(20,631)
Interest and other income, net	455	70
Interest and other expense, net	(1,395)	(1,050)
Net income/(loss)	$ 10,845	$ (21,611)
Net income/(loss) per share attributable to common shareholders:		
Basic and diluted	$ 0.19	$ (0.38)
Weighted average number of shares used in net income/(loss) per share calculations:		
Basic and diluted	56,351,647	56,305,049

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

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,782	$ 32,190
Marketable securities, current	2,889	28,859
Prepaid expenses	2,009	3,459
Grants revenue receivable	2,838	—
Other current assets	5,106	3,790
Total current assets	51,624	68,298
Operating lease right-of-use assets	10,652	11,132
Property and equipment, net	12,814	14,632
Other assets	3,415	3,486
Total assets	$ 78,505	$ 97,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,718	$ 504
Accrued liabilities	5,542	8,823
Deferred revenue, current	19,354	45,573
Other current liabilities	2,286	2,182
Total current liabilities	29,900	57,082
Deferred revenue, long-term	1,156	5,904
Long-term debt, net of current portion	36,402	36,168
Operating lease liabilities	11,635	12,231
Other liabilities	1,322	1,295
Total liabilities	80,415	112,680
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value: Authorized: 2,000,000 shares at March 31, 2023 and December 31, 2022; issued and outstanding: 250 shares at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value: Authorized: 150,000,000 shares at March 31, 2023 and December 31, 2022; issued and outstanding: 56,351,647 shares at March 31, 2023 and December 31, 2022	56	56
Additional paid-in capital	431,956	429,646
Accumulated other comprehensive income/(loss)	1	(66)
Accumulated deficit	(433,923)	(444,768)
Total stockholders' deficit	(1,910)	(15,132)
Total liabilities and stockholders' deficit	$ 78,505	$ 97,548