

**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):
Aug 4, 2022**

APPLIED MOLECULAR TRANSPORT INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39306
(Commission
File Number)

81-4481426
(IRS Employer
Identification No.)

450 East Jamie Court
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)
(650) 392-0420
(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
Common Stock, par value \$0.0001 per share	AMTI	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 Conditions.

On Aug 4, 2022, Applied Molecular Transport Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2022. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Applied Molecular Transport Inc. dated Aug 4, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

APPLIED MOLECULAR TRANSPORT INC.

By: /s/ Tahir Mahmood
Tahir Mahmood, Ph.D.
Co-Founder and Chief Executive Officer

Date: Aug 4, 2022

Applied Molecular Transport Reports Second Quarter 2022 Financial Results and Provides Corporate Update

- *Announced positive top-line data for AMT-101 FILLMORE Phase 2 trial in chronic pouchitis*
- *Orphan indication with no FDA-approved products*
- *Company granted end of Phase 2 meeting with FDA to discuss advancing into Phase 3 development*

Announced top-line data for AMT-101 MARKET Phase 2 combination trial in patients with moderate-to-severe ulcerative colitis (UC)

- *Post hoc analysis suggests combination treatment earlier in the course of disease may be beneficial*
- *Further analysis of patients with shorter duration of UC ongoing*

Anticipate Phase 2 top-line readout for oral AMT-101 in UC monotherapy in H2 2022, consistent with previous guidance

SOUTH SAN FRANCISCO, Calif., August 4, 2022 -- Applied Molecular Transport Inc. (Nasdaq: AMTI) (AMT), a clinical-stage biopharmaceutical company, today provided a corporate update and reported financial results for the second quarter ended June 30, 2022.

“We were pleased to recently announce that the company has been granted an end of Phase 2 meeting with FDA, based on the positive top-line data from our FILLMORE monotherapy trial in patients with chronic pouchitis,” said Tahir Mahmood, Ph.D., chief executive officer and co-founder of AMT. “The company remains focused on Phase 3 preparation for this important indication, and also looks forward to our remaining two top-line readouts for oral AMT-101 later this year and in 2023.”

Recent Business Highlights and Anticipated Milestones

- Announced positive Phase 2 top-line data in the AMT-101 FILLMORE monotherapy trial for patients with chronic pouchitis, an orphan indication with no FDA-approved products
 - Company granted end of Phase 2 meeting with FDA to discuss advancing to Phase 3
 - AMT-101 demonstrated favorable clinical activity and appeared safe and well-tolerated through the 12-week treatment period, in the most difficult-to-treat IBD patients where rapid, symptomatic improvement is critical
 - Met pre-specified efficacy endpoints, and achieved meaningful responses in stool frequency and histologic healing in both the 3mg and 10mg dosage groups
 - Independent DMC recommended advancing to Phase 3 with the 3 mg dose in chronic pouchitis
 - Announced Phase 2 top-line data in the AMT-101 MARKET combination trial with anti-TNF α in biologic-naïve patients with moderate-to-severe UC
 - Post hoc analysis suggests combination treatment earlier in the course of disease may be beneficial
 - Further analysis of patients with shorter duration of UC < 5 years ongoing
 - AMT-101 appeared safe and well-tolerated through the 8-week treatment period
 - Two ongoing Phase 2 trials for AMT-101, a GI-selective, oral fusion of IL-10 and AMT’s proprietary carrier molecule:
 - LOMBARD monotherapy trial for biologic-naïve and experienced patients with moderate-to-severe UC; Top-line data readout anticipated in H2 2022
 - CASTRO combination trial with anti-TNF α for patients with RA who are partial or non-responders to anti-TNF α therapy; Top-line data readout anticipated in 2023
 - Aligned senior management to support the recently announced strategic plan and late-stage focus of the company
 - Shawn Cross named president and chief operating officer
 - Brandon Hants assumed role of chief financial officer
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Financial Results for the Second Quarter Ended June 30, 2022

Research and development (R&D) expenses. Total R&D expenses for the second quarter of 2022 were \$25.9 million, compared to \$16.5 million for the same period in 2021. The overall increase was primarily related to higher expenses associated with clinical trials, increased headcount, facilities-related expenses and materials. Total R&D expenses for the second quarter of 2022 included nonrecurring charges related to the changes in its strategic plan of \$3.1 million announced May 18, 2022.

General and administrative (G&A) expenses. Total G&A expenses for the second quarter of 2022 were \$10.1 million, compared to \$7.1 million for the same period in 2021. The overall increase was primarily due to increased headcount, professional fees and facilities-related expenses. Total G&A expenses for the second quarter of 2022 included nonrecurring charges related to the strategic plan of \$0.7 million.

Net loss. Net loss for the second quarter of 2022 was \$35.9 million, compared to \$23.6 million for the same period in 2021. Stock-based compensation and depreciation and amortization for the second quarter of 2022 was \$6.5 million, compared to \$5.1 million for the same period in 2021.

Cash, cash equivalents, and investments. As of June 30, 2022, cash and cash equivalents were \$95.8 million. The Company believes its cash and cash equivalents will be sufficient to allow the Company to fund its current operating plan for at least the next twelve months.

About AMT-101

AMT-101 is a novel GI-selective, oral fusion of IL-10 and AMT's proprietary carrier molecule, currently in development in Phase 2 clinical trials for chronic pouchitis, UC and RA. AMT-101 is designed to cross the intestinal epithelial (IE) barrier with limited entry into the bloodstream, thereby focusing IL-10 at the primary site of inflammation in IBD, along the intestinal tissue lamina propria, potentially avoiding the side effects observed with systemic administration.

About Applied Molecular Transport Inc.

AMT is a clinical-stage biopharmaceutical company developing novel oral biologic product candidates, by leveraging its technology platform to design and advance a multi-product pipeline to treat autoimmune, inflammatory, metabolic and other diseases. AMT is developing its oral biologic product candidates in patient-friendly oral dosage forms that are designed to either target local intestinal tissue or enter systemic circulation to precisely address the relevant pathophysiology of disease. AMT's proprietary technology platform allows it to exploit existing natural cellular trafficking pathways to facilitate the active transport of diverse therapeutic modalities across the IE barrier. Active transport is an efficient mechanism that uses the cell's own machinery to transport materials across the IE barrier.

AMT's headquarters, internal GMP manufacturing and lab facilities are located in South San Francisco, CA. For additional information on AMT, please visit www.appliedmt.com.

Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements including statements relating to AMT's plans, expectations, forecasts and future events. Such forward-looking statements include, but are not limited to, the potential of, and expectations regarding AMT's technology platform and the extent to which it may enable the development of new products and AMT's internal manufacturing capabilities, statements regarding scaling our organization, growth of clinical activities, or pipeline expansion, statements regarding the optimization or expansion of our product development plans or the design of future clinical trials, statements regarding the potential of AMT-101, AMT-126, AMT's respiratory carrier technology or regarding AMT-101 and AMT-126 clinical trials, including the timing of data readouts from such trials, advancing product candidates to future phases of development, and program updates, milestones for such trials, and our ability to replicate past clinical development strategies, statements regarding the potential for AMT's product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and assumptions regarding the biological mode of action of our product candidates and the potential to avoid side effects with our product candidates. In some cases, you can identify forward-looking statements by terminology such as "believe," "estimate," "intend," "may," "plan," "potentially," "will," "expect," "enable," "likely" or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Actual events, trends or results could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements based on various factors. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in AMT's Annual and Quarterly Reports on Form 10-K and 10-Q filed with the Securities and Exchange Commission (the "SEC"), and AMT's future reports to be filed with the SEC. These forward-looking statements are made as of the date of this press release, and AMT assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

Applied Molecular Transport Inc.
Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,830	\$ 159,821
Prepaid expenses	4,347	6,685
Other current assets	1,131	594
Total current assets	101,308	167,100
Property and equipment, net	9,400	6,998
Operating lease right-of-use assets, net	34,512	38,142
Finance lease right-of-use assets, net	694	652
Restricted cash	1,025	1,025
Other assets	323	121
Total assets	<u>\$ 147,262</u>	<u>\$ 214,038</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,313	\$ 2,211
Accrued expenses	9,616	8,226
Operating lease liabilities, current	4,018	3,584
Finance lease liabilities, current	262	237
Total current liabilities	16,209	14,258
Operating lease liabilities	32,932	35,785
Finance lease liabilities	125	167
Other liabilities	244	241
Total liabilities	49,510	50,451
Commitments and contingencies		
Stockholders' equity:		
Common stock	4	4
Additional paid-in capital	415,913	403,228
Accumulated other comprehensive income	—	—
Accumulated deficit	(318,165)	(239,645)
Total stockholders' equity	97,752	163,587
Total liabilities and stockholders' equity	<u>\$ 147,262</u>	<u>\$ 214,038</u>

Applied Molecular Transport Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 25,909	\$ 16,534	\$ 57,148	\$ 31,415
General and administrative	10,113	7,093	21,450	12,692
Total operating expenses	36,022	23,627	78,598	44,107
Loss from operations	(36,022)	(23,627)	(78,598)	(44,107)
Interest income, net	75	59	72	99
Other income (expense), net	2	(62)	6	(84)
Net loss	\$ (35,945)	\$ (23,630)	\$ (78,520)	\$ (44,092)
Net loss per share, basic and diluted	\$ (0.93)	\$ (0.62)	\$ (2.03)	\$ (1.20)
Weighted-average shares of common stock outstanding, basic and diluted	38,748,741	38,128,095	38,695,350	36,680,973
Comprehensive loss:				
Net loss	\$ (35,945)	\$ (23,630)	\$ (78,520)	\$ (44,092)
Other comprehensive loss:				
Unrealized loss on investments	—	(19)	—	(21)
Total comprehensive loss	\$ (35,945)	\$ (23,649)	\$ (78,520)	\$ (44,113)

Refer to the Company's applicable SEC filings for previously reported periods.

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