

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 10, 2021

**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)

1 Tower Place, Suite 850  
South San Francisco, CA 94080  
(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 (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:

Title of each class	Trading Symbol	Name of exchange on which registered
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 November 10, 2021, Applied Molecular Transport Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2021. 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	<a href="#">Press Release of Applied Molecular Transport Inc. dated November 10, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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## 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: November 10, 2021

## Applied Molecular Transport Reports Third Quarter 2021 Financial Results and Provides Corporate Update

*Top-line data readout for oral AMT-101 Phase 2 MARKET combination trial with anti-TNF $\alpha$  in ulcerative colitis (UC) expected in H1 2022*

*Top-line data readouts from three additional oral AMT-101 Phase 2 trials, consistent with previous guidance*

- *FILLMORE monotherapy trial in pouchitis in H1 2022*
- *LOMBARD monotherapy trial in UC in H1 2022*
- *CASTRO combination trial with anti-TNF $\alpha$  in rheumatoid arthritis (RA) in H2 2022*

*Phase 1 enrollment ongoing for second product candidate, oral AMT-126, with program update in H1 2022*

SOUTH SAN FRANCISCO, Calif., November 10, 2021 -- Applied Molecular Transport Inc. (Nasdaq: AMTI) (AMT), a clinical-stage biopharmaceutical company, today provided a corporate update and reported financial results for the third quarter ended September 30, 2021.

“I recognize the commitment of the AMT team as we drive towards significant milestones over the next 12 months,” said Tahir Mahmood, Ph.D., chief executive officer and co-founder of AMT. “We are excited about the broad potential of our two product candidates, AMT-101 and AMT-126, for treating intestinal and systemic inflammatory indications and other diseases.”

### Recent Business Highlights and Anticipated Milestones

- Hosted virtual Research & Development Day to highlight novel oral biologics technology platform, clinical programs and research activities:
  - Announced new respiratory carrier technology and presented preclinical data on the approach
  - Featured distinguished IBD and rheumatology key opinion leaders
- Actively enrolling and dosing in four Phase 2 trials for AMT-101, a GI-selective, oral IL-10 fusion:
  - MARKET combination trial of oral AMT-101 with anti-TNF $\alpha$  in biologic-naïve patients with moderate-to-severe UC; Top-line data readout in H1 2022
    - Following the Company’s R&D Day event, the Company was notified of a potential imbalance in the trial’s planned 1:1 randomization. Upon confirmation of the imbalance, the Company now anticipates increasing total enrollment from 30 patients to between 40 and 50 patients. The trial has been and continues to be blinded.
  - FILLMORE monotherapy trial for patients with chronic pouchitis; Top-line data readout in H1 2022
  - LOMBARD monotherapy trial for biologic-naïve and experienced patients with moderate-to-severe UC; Top-line data readout in H1 2022
  - CASTRO combination trial of oral AMT-101 with anti-TNF $\alpha$  for patients with RA who are partial or non-responders to anti-TNF $\alpha$  therapy; Top-line data readout in H1 2022
- Enrollment ongoing in Phase 1 trial with AMT-126, a GI-selective, oral IL-22 fusion:
  - Phase 1 development plan includes healthy volunteers and patients
  - Broad potential in multiple indications in patients with impaired intestinal epithelial barrier function
  - Program update from oral AMT-126 in H1 2022
- Appointed Holly Schachner, M.D. a seasoned and accomplished industry veteran to the company’s Board of Directors
- Presented additional positive data from oral AMT-101 Phase 1b multiple ascending dose trial in UC patients at the ECCO’21 Virtual Congress in July 2021

### Anticipated Upcoming Milestones

- Top-line data readouts from the four oral AMT-101 Phase 2 trials as follows:
    - MARKET UC combination with anti-TNF $\alpha$  in [H1] 2022
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- Following the Company's R&D Day, the Company identified an imbalance in the trial's planned 1:1 randomization. To address this imbalance, the Company is increasing enrollment above the initial target of approximately 30 patients. Per trial protocol, the trial has been and continues to be blinded. [For additional information, please refer to the Company's corresponding 10-Q filing.]
  - FILLMORE pouchitis monotherapy in H1 2022
  - LOMBARD UC monotherapy in H1 2022
  - CASTRO RA combination with anti-TNF $\alpha$  in H2 2022
- Program update from oral AMT-126 Phase 1 trial in H1 2022

### **Financial Results for the Third Quarter Ended September 30, 2021**

**Research and development (R&D) expenses.** Total R&D expenses for the third quarter of 2021 were \$18.4 million, compared to \$13.4 million for the same period in 2020. The overall increase was primarily related to an increase in expenses associated with compensation due to an increase in headcount, along with increases in facility related expenses, clinical trials, and materials, partially offset by a decrease in preclinical studies and contract manufacturing.

**General and administrative (G&A) expenses.** Total G&A expenses for the third quarter of 2021 were \$7.6 million, compared to \$3.4 million for the same period in 2020. The overall increase was primarily related to an increase of \$3.0 million in personnel and administrative costs due to an increase in headcount and an increase of \$1.0 million in professional fees.

**Net loss.** Net loss for the third quarter of 2021 was \$26.0 million, compared to \$16.8 million for the same period in 2020.

**Cash, cash equivalents, and investments.** As of September 30, 2021, cash, cash equivalents, and investments were \$182.5 million.

#### **About AMT-101**

AMT-101 is a novel GI-selective, oral fusion of hIL-10 and AMT's proprietary carrier molecule, currently in development in four Phase 2 clinical trials in inflammatory bowel diseases and rheumatoid arthritis. AMT-101 is designed to cross the intestinal epithelial (IE) barrier with limited entry into the bloodstream, thereby focusing hIL-10 at the primary site of inflammation for UC and potentially avoiding the side effects observed with systemic administration. By design, AMT-101 is actively transported through the IE barrier into the GI tissue, the primary site of inflammation in UC.

#### **About AMT-126**

AMT-126 is a novel GI-selective, oral fusion of hIL-22 and AMT's proprietary carrier molecule currently in development for diseases related to IE barrier defects. IL-22 is a cytokine that repairs structural and functional defects of the IE barrier and induces microbial defense. AMT-126 is designed to act locally on the epithelial cells of the intestinal tissue, thereby repairing the IE barrier and supporting mucosal healing, potentially translating into clinically meaningful improvements in a broad range of GI-focused, peripheral inflammatory and other diseases.

#### **About Applied Molecular Transport Inc.**

Applied Molecular Transport Inc. is a clinical-stage biopharmaceutical company leveraging its proprietary technology platform to design and develop a pipeline of novel oral biologic product candidates to treat autoimmune, inflammatory, metabolic, and other diseases. 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 believes that its ability to exploit this mechanism is a key differentiator of its approach. AMT is developing additional oral biologic product candidates in patient-friendly oral forms that are designed to either target local intestinal tissue or enter systemic circulation to precisely address the relevant biology of a disease.

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](http://www.appliedmt.com).

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**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 AMT's internal manufacturing capabilities, 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 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" 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.

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

	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 152,455	\$ 5,843
Short-term investments	30,069	124,026
Prepaid expenses	4,503	1,311
Other current assets	634	321
Total current assets	187,661	131,501
Property and equipment, net	6,445	8,447
Operating lease right-of-use assets, net	11,173	—
Finance lease right-of-use assets, net	700	—
Restricted cash	1,025	108
Other assets	52	127
Total assets	<u>\$ 207,056</u>	<u>\$ 140,183</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,411	\$ 3,174
Accrued expenses	5,915	4,173
Operating lease liabilities, current	2,164	—
Finance lease liabilities, current	242	—
Deferred rent, current	—	83
Capital lease obligations, current	—	232
Total current liabilities	9,732	7,662
Operating lease liabilities	9,582	—
Finance lease liabilities	221	—
Deferred rent	—	444
Capital lease obligations	—	404
Total liabilities	19,535	8,510
Commitments and contingencies		
Stockholders' equity:		
Common stock	4	4
Additional paid-in capital	396,958	271,000
Accumulated other comprehensive income	1	27
Accumulated deficit	(209,442)	(139,358)
Total stockholders' equity	187,521	131,673
Total liabilities and stockholders' equity	<u>\$ 207,056</u>	<u>\$ 140,183</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 18,350	\$ 13,395	\$ 49,765	\$ 39,185
General and administrative	7,641	3,428	20,333	8,404
Total operating expenses	25,991	16,823	70,098	47,589
Loss from operations	(25,991)	(16,823)	(70,098)	(47,589)
Interest income, net	5	59	104	187
Other expense, net	(6)	(29)	(90)	(81)
Net loss	\$ (25,992)	\$ (16,793)	\$ (70,084)	\$ (47,483)
Net loss per share, basic and diluted	\$ (0.68)	\$ (0.48)	\$ (1.88)	\$ (2.53)
Weighted-average shares of common stock outstanding, basic and diluted	38,437,096	34,767,308	37,273,178	18,770,153
Comprehensive loss:				
Net loss	\$ (25,992)	\$ (16,793)	\$ (70,084)	\$ (47,483)
Other comprehensive (loss) income:				
Unrealized (loss) gain on investments	(5)	29	(26)	37
Amounts recognized for net realized gains included in net loss	—	—	—	(19)
Total comprehensive loss	\$ (25,997)	\$ (16,764)	\$ (70,110)	\$ (47,465)

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

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