

**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):
August 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.)

1 Tower Place, Suite 850
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)
(650) 392-0420
(Registrant's telephone number, including area code)

Not Applicable
(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 August 10, 2021, Applied Molecular Transport Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 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 | Press Release of Applied Molecular Transport Inc. dated August 10, 2021 |

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: August 10, 2021

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

Top-line data readouts expected from four Phase 2 trials of oral AMT-101, consistent with previous guidance

- Combination trial of AMT-101 with anti-TNF α in moderate-to-severe ulcerative colitis (UC) patients in the fourth quarter of 2021;
- Monotherapy trial in pouchitis, combination trial with anti-TNF α in rheumatoid arthritis (RA) and monotherapy trial in UC in 2022

Phase 1 enrollment on-going for second product candidate, oral AMT-126, with top-line data readout expected in 2022

Strengthened balance sheet with successful follow-on offering in April with net proceeds of approximately \$113 million; As of June 30, 2021, cash, cash equivalents, and investments of approximately \$200 million

Virtual R&D Day planned for October 15, 2021, to discuss platform technology, clinical programs, and research activities

SOUTH SAN FRANCISCO, Calif., August 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 second quarter ended June 30, 2021.

“We have continued to advance our portfolio of transformational oral biologic therapeutics, with both AMT-101 and AMT-126 in the clinic,” said Tahir Mahmood, Ph.D., chief executive officer and co-founder of AMT. “We were pleased to further strengthen our balance sheet with a successful follow-on offering in April. These proceeds enable us to accelerate development of our pipeline of promising therapeutics. We believe that our programs in the clinic, AMT-101 and AMT-126, have broad potential for treating intestinal and systemic inflammatory indications and other diseases. We look forward to top-line readouts from our AMT-101 Phase 2 trials beginning in the fourth quarter of this year, and top-line AMT-126 Phase 1 data in 2022. We believe the next 12 months will be a data-rich and execution-focused period for the company.”

Recent Business Highlights

- 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:
 - After 14 days of treatment, once daily, oral AMT-101 was safe and well tolerated, and demonstrated trends of improvement in objective measures of inflammation: fecal calprotectin, CRP, and histology
 - Key findings support our thesis that oral AMT-101 actively exerts immunomodulatory effect resulting in local and systemic benefit
 - Microbiome analyses demonstrate enhancement of favorable enteric commensal bacteria, known to be correlated with restoration of intestinal immune homeostasis
 - Enrollment ongoing 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 α in biologic-naïve patients with moderate-to-severe UC
 - FILLMORE monotherapy trial for patients with chronic pouchitis
 - CASTRO combination trial of oral AMT-101 with anti-TNF α for patients with RA who are partial or non-responders to anti-TNF α therapy
 - LOMBARD monotherapy trial for biologic-naïve and experienced patients with moderate-to-severe UC
 - Enrollment ongoing in Phase 1a trial in healthy volunteers for AMT-126, a GI-selective, oral IL-22 fusion:
 - Expect development plan to resemble AMT-101 approach with broad potential in multiple indications
 - Plan to conduct a Phase 1b trial in patients with impaired intestinal epithelial barrier function
 - Closed an underwritten public offering in April of 2,875,000 shares of our common stock, at a public offering price of \$42.00 per share, resulting in net proceeds of \$112.8 million
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Anticipated Upcoming Milestones

- Top-line data readouts from four oral AMT-101 Phase 2 trials in Q4 2021 and into 2022
- Top-line data readout from oral AMT-126 Phase 1 trial in 2022
- Virtual R&D Day planned for October 15, 2021 to discuss platform technology, clinical programs, including study designs, and research activities
- Supporting growth of clinical activities and pipeline expansion by combining corporate headquarters, research labs and oral biologics GMP manufacturing facility in a single site in South San Francisco, CA in Q4 2021

Financial Results for the Second Quarter Ended June 30, 2021

Research and development (R&D) expenses. Total R&D expenses for the second quarter of 2021 were \$16.5 million, compared to \$12.8 million for the same period in 2020. The increase was related to an increase in expenses associated with clinical trials, compensation and facility related expenses, offset by a decrease in materials, preclinical studies and contract manufacturing.

General and administrative (G&A) expenses. Total G&A expenses for the second quarter of 2021 were \$7.1 million, compared to \$2.5 million for the same period in 2020. The increase was primarily due to an increase of \$3.2 million in personnel and administrative costs due to an increase in headcount and an increase of \$1.3 million in professional fees.

Net loss. Net loss for the second quarter of 2021 was \$23.6 million, compared to \$15.4 million for the same period in 2020.

Cash, cash equivalents, and investments. As of June 30, 2021, cash, cash equivalents, and investments were \$199.5 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 intestinal epithelial (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.

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 and AMT-126 or regarding AMT-101 and AMT-126 clinical trials, including the timing of data readouts from 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.

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

| | June 30, 2021 | December 31, 2020 |
|--|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 159,455 | \$ 5,843 |
| Short-term investments | 40,065 | 124,026 |
| Prepaid expenses | 5,969 | 1,311 |
| Other current assets | 419 | 321 |
| Total current assets | 205,908 | 131,501 |
| Property and equipment, net | 6,606 | 8,447 |
| Operating lease right-of-use assets, net | 9,853 | — |
| Finance lease right-of-use assets, net | 748 | — |
| Restricted cash | 1,025 | 108 |
| Other assets | 127 | 127 |
| Total assets | <u>\$ 224,267</u> | <u>\$ 140,183</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,392 | \$ 3,174 |
| Accrued expenses | 3,910 | 4,173 |
| Operating lease liabilities, current | 2,608 | — |
| Finance lease liabilities, current | 239 | — |
| Deferred rent, current | — | 83 |
| Capital lease obligations, current | — | 232 |
| Total current liabilities | 8,149 | 7,662 |
| Operating lease liabilities | 7,746 | — |
| Finance lease liabilities | 282 | — |
| Deferred rent | — | 444 |
| Capital lease obligations | — | 404 |
| Total liabilities | 16,177 | 8,510 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity: | | |
| Common stock, \$0.0001 par value, 450,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 38,350,990 and 35,121,360 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively | 4 | 4 |
| Additional paid-in capital | 391,530 | 271,000 |
| Accumulated other comprehensive income | 6 | 27 |
| Accumulated deficit | (183,450) | (139,358) |
| Total stockholders' equity | 208,090 | 131,673 |
| Total liabilities and stockholders' equity | <u>\$ 224,267</u> | <u>\$ 140,183</u> |

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

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

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|-------------|------------------|-------------|
| | June 30, | | June 30, | |
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | \$ 16,534 | \$ 12,836 | \$ 31,415 | \$ 25,790 |
| General and administrative | 7,093 | 2,487 | 12,692 | 4,976 |
| Total operating expenses | 23,627 | 15,323 | 44,107 | 30,766 |
| Loss from operations | (23,627) | (15,323) | (44,107) | (30,766) |
| Interest income, net | 59 | 45 | 99 | 128 |
| Other expense, net | (62) | (101) | (84) | (52) |
| Net loss | \$ (23,630) | \$ (15,379) | \$ (44,092) | \$ (30,690) |
| Net loss per share, basic and diluted | \$ (0.62) | \$ (1.11) | \$ (1.20) | \$ (2.88) |
| Weighted-average shares of common stock outstanding, basic and diluted | 38,128,095 | 13,869,040 | 36,680,973 | 10,643,240 |
| Comprehensive loss: | | | | |
| Net loss | \$ (23,630) | \$ (15,379) | \$ (44,092) | \$ (30,690) |
| Other comprehensive (loss) income: | | | | |
| Unrealized (loss) gain on investments | (19) | 2 | (21) | 8 |
| Amounts recognized for net realized gains included in net loss | — | (19) | — | (19) |
| Total comprehensive loss | \$ (23,649) | \$ (15,396) | \$ (44,113) | \$ (30,701) |

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