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): July 6, 2022

APPLIED MOLECULAR TRANSPORT INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39306**	**82-4481426**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

450 East Jamie Court
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: (650) 392-0420

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:

☐ 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, 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 8.01 Other Events.

On July 6, 2022, Applied Molecular Transport Inc. (the "Company") issued a press release announcing top-line Phase 2 results from the Company's MARKET combination trial for AMT-101 in patients with moderate-to-severe ulcerative colitis.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated July 6, 2022, issued by Applied Molecular Transport Inc.
104	Cover Page Interactive Data File (the cover page XBRL tags are 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 thereunto duly authorized.

APPLIED MOLECULAR TRANSPORT INC.

Date: July 6, 2022

By: /s/ Earl Douglas
Earl Douglas
Executive Vice President, General Counsel and Secretary

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Applied Molecular Transport Announces Top-line Phase 2 Results from MARKET Combination Trial of Oral AMT-101 in Patients with Moderate-to-Severe Ulcerative Colitis

- Similar clinical remission rates observed of 31.8% (7/22) in patients receiving combination (AMT-101 and adalimumab) versus 33.3% (9/27) in patients receiving placebo plus adalimumab at week 8
- Post hoc analysis of patients with shorter duration of ulcerative colitis (UC) < 5 years showed clinical remission rate of 43.8% (7/16) in patients receiving combination versus 15.4% (2/13) in patients receiving adalimumab alone, suggesting combination treatment earlier in the course of disease may be beneficial
- AMT-101 appeared safe and well-tolerated

- Company will host live conference call and webcast today, July 6, 2022, at 8:30 a.m. ET (5:30 a.m. PT)

SOUTH SAN FRANCISCO, Calif., July 6, 2022 — Applied Molecular Transport Inc. (Nasdaq: AMTI) (AMT) today announced top-line Phase 2 results from the MARKET combination trial for AMT-101 in biologic-naïve patients with moderate-to-severe UC. AMT-101 is an investigational, once-daily, GI-selective, oral fusion of IL-10 and AMT's proprietary carrier molecule.

MARKET Results

In the MARKET trial, patients received either once-daily oral AMT-101 3mg in combination with adalimumab (sub-cutaneous administration per the approved UC label), or adalimumab alone (with placebo). The objectives of the MARKET trial were to assess the safety and efficacy of AMT-101 in combination with anti-TNFα therapy (adalimumab) in patients with moderate-to-severe UC. The key efficacy endpoint of clinical remission was measured at 8 weeks.

The clinical remission rate in the adalimumab alone arm was higher than historical anti-TNFα monotherapy benchmarks, and the data from the MARKET trial did not demonstrate added clinical benefit in the combination arm compared to the adalimumab alone arm at week 8. Of the 49 evaluable patients, 31.8% (7/22) of patients treated in the combination arm (AMT-101 3mg with adalimumab) achieved clinical remission versus 33.3% (9/27) in patients receiving adalimumab alone at week 8. Clinical remission is defined as Mayo endoscopic subscore of 0 or 1, rectal bleeding subscore of 0 and stool frequency subscore of 0 or 1.

AMT-101 appeared safe and well-tolerated. Treatment emergent adverse events (TEAEs) were mostly mild to moderate, with one serious adverse event (SAE) observed, worsening of UC, which was determined to be unrelated to study treatment.

Overall patient demographics were balanced between the two arms with the exception of patients in the combination arm having much shorter duration of UC history versus patients in adalimumab alone arm. Based on this observation, we conducted a post hoc sub-group analysis to explore the potential effect of duration of UC history on clinical remission.

Sub-group analysis revealed that patients with a shorter duration of UC (< 5 years) had clinical remission rates of 43.8% (7/16) in the combination arm versus 15.4% (2/13) in the adalimumab alone arm. In patients with longer duration UC (≥ 5 years), clinical remission rates were 0.0% (0/6) in the combination arm versus 50.0% (7/14) in patients receiving adalimumab alone.

These data suggest that combination treatment with AMT-101 earlier in the course of UC may be more beneficial than anti-TNFα alone within 5 years of diagnosis. Further evaluation and analyses are ongoing.

Clinical Remission* (at week 8)	n (%) Patients AMT-101 3 mg with adalimumab	Placebo with adalimumab
Overall	7/22 (31.8%)	9/27 (33.3%)
Patients with UC < 5 years	7/16 (43.8%)	2/13 (15.4%)
Patients with UC ≥ 5 years	0/6 (0.0%)	7/14 (50.0%)

* *Mayo endoscopic subscore of 0 or 1 (blinded central read), rectal bleeding subscore of 0 and stool frequency subscore of 0 or 1*

The Company plans to present full trial results at an upcoming medical conference.

“While the clinical remission rates for combination therapy surpassed previous anti-TNFα monotherapy and UC clinical remission benchmarks, we did not anticipate the high rate of remission in the adalimumab alone arm. The observation of an unequal duration of UC between the trial arms led us to perform a post hoc sub-group analysis which supports additive efficacy with the combination in patients earlier in their course of UC. These data will further inform our future development plans for AMT-101 in combination therapy and we plan to discuss next steps with FDA. I am pleased by the growing body of data supporting clinical efficacy of AMT-101 as a monotherapy as well as in combination therapy.” said Bittoo Kanwar, M.D., chief medical officer of AMT. “We thank our patients and sites for participating in the MARKET trial.”

“As a gastroenterologist specializing in IBD, I am encouraged by the results of this trial that suggest that earlier treatment with AMT-101 combination therapy may have an additive benefit to patients with UC. This supports previously reported data by our laboratory highlighting the potential for combination therapy with IL-10 in IBD,” said Geert D’Haens, M.D., Ph.D., Professor of Medicine and Gastroenterology at the Academic Medical Centre, University of Amsterdam. Dr. D’Haens is co-founder of the European Crohn’s and Colitis Organization (ECCO) and Lead Principal Investigator of the MARKET trial.

AMT anticipates a number of milestones for its AMT-101 development program in IBD. For chronic pouchitis, FDA has granted an end of Phase 2 meeting for AMT-101 to discuss Phase 3 development. The company also anticipates top-line results from its ongoing AMT-101 Phase 2 LOMBARD monotherapy trial for UC in the second half of 2022.

Conference Call & Webcast Information

AMT will host a live investor conference call and webcast today, July 6, 2022, at 8:30 a.m. ET (5:30 a.m. PT).

To join the conference call via phone and participate in the live Q&A session, please pre-register online here to receive a telephone number and unique passcode required to enter the call. A live webcast will be available on the Events page of the Applied Molecular Transport website at https://ir.appliedmt.com/news-events/events. An archived replay will be available for 30 days following the event.

About MARKET

MARKET is a Phase 2 double-blinded, placebo-controlled trial that evaluated the safety and efficacy of orally administered AMT-101 in combination with anti-TNFα (adalimumab) over 8 weeks in patients with moderate-to-severe UC. The MARKET trial randomized 51 patients with 8-week once-daily dosing to either oral AMT-101 3mg and adalimumab or adalimumab alone (plus placebo).

About Ulcerative Colitis

UC is a chronic inflammatory bowel disease that causes inflammation in the gastrointestinal (GI) tract. Symptoms may include, but are not limited to, diarrhea, abdominal pain, bloody stools, rectal bleeding, weight loss and fatigue. UC affects millions of people worldwide and may also profoundly impact quality of life. There remains a significant unmet need for safer and more effective oral therapies.

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 four 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 biologic product candidates in patient friendly oral dosage forms. AMT's product candidates are designed to precisely target the relevant pathophysiology of disease. AMT's proprietary technology platform is incorporated in its product candidates, exploiting existing natural cellular trafficking pathways to drive the active transport of diverse therapeutic modalities across the IE barrier. Active transport is an efficient mechanism that utilizes 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, statements regarding AMT-101 including the potential of AMT-101, the ability of AMT-101 to avoid side effects, the milestones for AMT-101, AMT-101's clinical trials including the timing of top-line results from the AMT-101 Phase 2 trials, the LOMBARD trial as a monotherapy for UC and the CASTRO trial in combination with anti-TNFα for, advancing AMT-101 to future phases of development and statements regarding our ability to obtain regulatory approval for AMT-101, and statements by AMT's chief medical officer. 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.

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