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): December 22, 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 December 22, 2022, Applied Molecular Transport Inc. (the "Company") issued a press release announcing top-line Phase 2 results from the Company's LOMBARD monotherapy trial of 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 December 22, 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: December 22, 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 LOMBARD Monotherapy Trial of Oral AMT-101 in Patients with Moderate-to-Severe Ulcerative Colitis

- Similar clinical remission rates observed in patients receiving AMT-101 monotherapy compared to placebo at week 12

- AMT-101 was well-tolerated

- Planned Phase 1b trial for the company's second clinical asset, AMT-126, in UC patients

- Exploring strategic partnership options to advance AMT-101 into Phase 3 in patients with chronic pouchitis

- Strong cash position of $76M reported in Q3 2022

SOUTH SAN FRANCISCO, Calif., December 22, 2022 — Applied Molecular Transport Inc. (Nasdaq: AMTI) (AMT) today announced top-line Phase 2 results from the LOMBARD monotherapy trial for AMT-101 in biologic-naïve and experienced patients with moderate-to-severe ulcerative colitis (UC). AMT-101 is an investigational, once-daily, GI-selective, oral fusion of IL-10 and AMT's proprietary carrier molecule. The clinical remission (CR) rate in patients treated with AMT-101 monotherapy was 17.1% (12/70 patients) compared to a CR rate of 20.0% (7/35 patients) with placebo, which was above the company's baseline assumption for placebo CR rates based on published data in moderate-to-severe UC patients.

"We thank our patients and sites for participating in the LOMBARD trial. While we are disappointed with the top-line results, we are seeking to better understand the unexpectedly high placebo rate of clinical remission in this moderate-to-severe population," said Bittoo Kanwar, M.D., chief medical officer of AMT. "Separately, we continue to be encouraged by the positive data generated with AMT-101 in chronic pouchitis, which has been granted Orphan Drug Designation in this indication. We will be seeking a partner to advance this program into Phase 3 and look forward to presenting additional pouchitis data at the European Crohn's and Colitis Organisation meeting in March 2023."

Tahir Mahmood, Ph.D., chief executive officer and co-founder of AMT, added, "Our platform technology has generated two clinical assets, and we look forward to advancing AMT-126, an oral fusion of AMT's proprietary carrier molecule and IL-22, which is a validated target, into a planned Phase 1b trial in UC. We remain focused on stepwise execution and will be judicious in deploying our resources and extending our cash runway."

AMT remains focused on developing its two clinical assets:

- Preparing AMT-126 (oral fusion of IL-22) for a Phase 1b trial in patients with moderate-to-severely active UC.
- Exploring a strategic partnership to advance AMT-101 into Phase 3 in chronic pouchitis and concluding the ongoing AMT-101 Phase 2 CASTRO combination trial in patients with rheumatoid arthritis (RA).

LOMBARD Results

In the LOMBARD trial, patients received once-daily oral AMT-101 3mg or placebo in a 2:1 ratio. The objectives of the LOMBARD trial were to assess the safety and efficacy of AMT-101 in patients with moderate-to-severe UC. The key efficacy endpoint of clinical remission was measured at 12 weeks.

Of the 105 patients, 17.1% (12/70) of patients treated in the monotherapy arm (AMT-101 3mg) achieved clinical remission versus 20.0% (7/35) in patients receiving placebo at week 12. Clinical remission is defined as Mayo endoscopic subscore of 0 or 1 (blinded central read), rectal bleeding subscore of 0 and stool frequency subscore of 0 or 1.

AMT-101 was well-tolerated. Treatment emergent adverse events (TEAEs) were mostly mild to moderate and were generally balanced between the two arms.

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

About LOMBARD

LOMBARD is a Phase 2 double-blinded, placebo-controlled trial that evaluated the safety and efficacy of orally administered AMT-101 monotherapy over 12 weeks in patients with moderate-to-severe UC. The LOMBARD trial randomized 105 patients with 12-week once-daily dosing to either oral AMT-101 3mg or placebo. Safety follow-up is on-going.

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 Pouchitis

Approximately 30% of patients with UC eventually require total colectomy. Ileal pouch-anal anastomosis (IPAA) is the surgical treatment of choice as it avoids permanent ileostomy and is associated with better quality of life outcomes. Up to 60,000 patients in the U.S. alone experience pouchitis, inflammation in the lining of the pouch, after IPAA surgery. Acute pouchitis often responds to antibiotic treatment but up to 50% of pouchitis patients develop chronic pouchitis where patients often relapse on or do not respond to antibiotic therapy. Pouchitis is characterized by clinical symptoms of excessive stool frequency, urgency, fecal incontinence, nocturnal seepage and lower abdominal pain. Pouchitis is an orphan indication with no current FDA-approved therapies.

About AMT-126

AMT-126 is a novel GI-selective, oral fusion of IL-22 and AMT's proprietary carrier molecule for diseases related to intestinal epithelial (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 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 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, statements relating to AMT's cash runway, the potential of, and expectations regarding AMT's technology platform, statements regarding AMT-101 and AMT-126 including the potential of AMT-101 and AMT-126, the ability of AMT-101 to avoid side effects, the milestones for AMT-101 and AMT-126, AMT-101 and AMT-126's clinical trials and the potential of a partnership to advance AMT-101, , and statements by AMT's chief medical officer and chief executive officer and co-founder. 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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