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): April 25, 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 April 25, 2022, Applied Molecular Transport Inc. (the "Company") issued a press release announcing positive Phase 2 top-line results from the Company's FILLMORE monotherapy trial for AMT-101 in patients with chronic pouchitis.

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 April 25, 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: April 25, 2022

By: /s/ Shawn Cross
Shawn Cross
Chief Financial Officer

APPLIED | MOLECULAR | TRANSPORT

Applied Molecular Transport Announces Positive Top-line Phase 2 Results from FILLMORE Trial of Oral AMT-101 in Patients with Chronic Pouchitis

- Met pre-specified efficacy endpoints in chronic pouchitis, a difficult-to-treat inflammatory bowel disease (IBD)
- AMT-101 demonstrated favorable clinical activity and appeared safe and well-tolerated, supporting potentially best-in-class profile
- Achieved clinically meaningful responses in stool frequency and histologic healing in both 3mg and 10mg dosage groups
- Independent Data Monitoring Committee (DMC) recommends advancing to Phase 3 in chronic pouchitis
- Further substantiates potential of AMT-101 and Company's oral biologics platform

- Investor conference call and webcast today at 8:30 a.m. ET (5:30 a.m. PT)

SOUTH SAN FRANCISCO, Calif., April 25, 2022 — Applied Molecular Transport Inc. (Nasdaq: AMTI) (AMT) today announced positive top-line Phase 2 results from the FILLMORE monotherapy trial for AMT-101 in patients with chronic pouchitis, an orphan indication with significant unmet medical need and no current FDA-approved therapies. AMT-101 is an investigational, once-daily, GI-selective, oral fusion of IL-10 and AMT's proprietary carrier molecule, which is also in development for the treatment of ulcerative colitis (UC) and rheumatoid arthritis (RA).

FILLMORE Results

The objectives of the FILLMORE trial were to assess the safety and efficacy of AMT-101 in severe chronic pouchitis patients and to select a dose for Phase 3. The trial was designed to measure two key pre-specified efficacy endpoints: 1) symptomatic improvement, as measured by stool frequency response, and 2) histologic healing, as measured by central read.

On the first measure, results from the trial demonstrated that 36.4% (8/22) of patients achieved stool frequency response, defined as a reduction of ≥ 3 stools and $\geq 30\%$ from baseline, OR $\leq$ post-colectomy normal. Rapid onset of stool frequency response was demonstrated as early as week 2 in both dosage groups and was maintained through the duration of treatment. Top-line interim data demonstrated additional symptomatic improvements in fecal urgency, incontinence and abdominal cramps. The proportion of patients achieving the symptomatic stool frequency response in both dosage groups exceeded the criteria for determining advancement into Phase 3.

On the second measure, 22.7% (5/22) of patients met the pre-specified histologic healing response of Geboes score ≤ 3.1, an objective assessment of disease improvement. FILLMORE patients had a median baseline Geboes score of 5.1, representing severe pouchitis with ulceration and tissue destruction. Both dosage groups demonstrated histologic healing response. Top-line endoscopic assessments, which may be less relevant in chronic pouchitis than in other IBD indications, were also performed, with modest directional improvements. Histology and endoscopy data were centrally read.

Pre-specified Efficacy Endpoint	Endpoint Definition	n(%) Patients Achieving Response AMT-101 3 mg (N=10)	AMT-101 10 mg (N=12)	Total (N=22)
Stool Frequency Response (%) at Week 12	Reduction of ≥ 3 stools and ≥ 30% from baseline, OR ≤ post-colectomy normal	4(40.0%)	4(33.3%)	8(36.4%)
Histologic Healing Response (%) at Week 12	Geboes score ≤ 3.1	2(20.0%)	3(25.0%)	5(22.7%)

AMT-101 appeared safe and well-tolerated. Treatment emergent adverse events (TEAEs) were mostly mild to moderate, with only one serious adverse event (SAE) observed, cytomegalovirus (CMV) infection, which was determined to be unrelated to study drug.

The FILLMORE independent DMC recommends advancing AMT-101 to Phase 3 with the 3mg dose in chronic pouchitis, based on its review of safety and efficacy data available to date. The DMC was comprised of leading experts from Yale University, Harvard University and its associated medical institutions.

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

“The results of the FILLMORE Phase 2 trial are compelling and demonstrate the activity of orally administered AMT-101 in chronic pouchitis,” said Brian Feagan, M.D., Professor of Medicine, Departments of Medicine, Division of Gastroenterology, Epidemiology and Biostatistics at Western University, Canada. “These data are impressive given that the patient population enrolled in the trial had advanced disease, with severe symptoms that negatively impact their quality of life. These data not only demonstrated objective histologic healing, but more importantly showed a rapid reduction in daily stool frequency and improvement in urgency, incontinence and abdominal cramps, key measures that are most important to patients and clinicians.”

“Given the severity of the disease and positive top-line results of the trial, we are excited to share these data with FDA and other regulatory agencies to advance AMT-101 development in chronic pouchitis,” said Bittoo Kanwar, M.D., chief medical officer of AMT. “We believe these data support the therapeutic potential of AMT-101 to treat diseases associated with mucosal immunology and inflammation. We thank our patients and sites for participating in the trial.”

AMT anticipates top-line results from its additional Phase 2 trials investigating oral AMT-101 as follows: the MARKET trial in combination with anti-TNFα for UC in the second quarter of 2022, the LOMBARD trial as a monotherapy for UC in the second half of 2022 and the CASTRO trial in combination with anti-TNFα for RA in the second half of 2022.

Conference Call & Webcast Information

AMT will host an investor conference call and live webcast today, April 25, 2022, at 8:30 a.m. ET (5:30 a.m. PT) to discuss the FILLMORE Phase 2 trial results.

When: April 25, 2022, 8:30 a.m. ET (5:30 a.m. PT)
Dial-in: (844) 422-9742 (United States) or (706) 758-6032 (International)
Conference ID: 5649019

Please join the conference call or webcast approximately 15 minutes early to register. The live webcast will be accessible via 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 FILLMORE

FILLMORE is a Phase 2 double-blinded trial that evaluated the safety and efficacy of orally administered AMT-101 monotherapy, over 12 weeks, in patients with chronic pouchitis. The FILLMORE trial randomized 22 patients to 3mg or 10mg of oral AMT-101. The trial was conducted across 33 sites and 11 countries in patients with daily stool frequency ≥ 6 (and > 3 stools per day more than baseline), Modified Pouchitis Disease Activity Index (mPDAI) score ≥ 5, and histological evidence of pouchitis (Geboes ≥ 3.1), among other entry criteria. Patients must have failed at least one round of antibiotic therapy and no lead-in or rescue antibiotic therapy was allowed.

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-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 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 is developing additional 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 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 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 or regarding AMT-101 clinical trials, including the timing of data readouts from such

trials including top-line results from the MARKET trial in combination with anti-TNFα for UC, the LOMBARD trial as a monotherapy for UC and the CASTRO trial in combination with anti-TNFα for RA, statements regarding the market potential of AMT's product candidates, advancing product candidates to future phases of development, statements regarding our ability to obtain regulatory approval for AMT's product candidates, 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, assumptions regarding the mechanism of action of our product candidates and the potential to avoid side effects with our product candidates, statements regarding the market opportunity for our product candidates 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.

Investor Relations Contact:
Andrew Chang
Head, Investor Relations & Corporate Communications
achang@appliedmt.com

Media Contacts:
Alexandra Santos
Wheelhouse Life Science Advisors
asantos@wheelhouselsa.com

Aljanae Reynolds
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com