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): May 18, 2022

AVALO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-37590		**45-0705648**
(Commission File Number)		**(IRS Employer Identification No.)**

540 Gaither Road, Suite 400, Rockville, Maryland 20850
(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (410) 522-8707

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, $0.001 Par Value	AVTX	Nasdaq Capital 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 May 18, 2022, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in the Company's Phase 2 PEAK (A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX-002 for the Treatment of **P**oorly Controlled Non-**E**osinophilic **A**sthma **K**) trial evaluating AVTX-002 for the treatment of non-eosinophilic asthma.

On May 24, 2022, the Company posted on its website an updated investor presentation (the "Investor Presentation"). The Investor Presentation will be used from time to time in meetings with investors. Copies of the press release and Investor Presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated May 18, 2022.
99.2	Investor Presentation.
104	The cover pages of this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURE

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.

AVALO THERAPEUTICS, INC.

Date: May 24, 2022

By: /s/ Christopher Sullivan
Christopher Sullivan
Chief Financial Officer

Avalo Therapeutics Announces First Patient Dosed in the Phase 2 PEAK Trial of AVTX-002 for the Treatment of Non- Eosinophilic Asthma (NEA)

- Topline results expected 4Q2022

WAYNE, Pa. AND ROCKVILLE, Md., May 18, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), announced that the first patient has been dosed in the company's Phase 2 PEAK (A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX- 002 for the Treatment of **P**oorly Controlled Non-**E**osinophilic **A**sthma **K**) trial evaluating AVTX-002 for the treatment of non-eosinophilic asthma (NEA).

"*Dosing the first patient in the Phase 2 PEAK trial brings us a step closer to delivering a new treatment option to these patients. Nearly half of all asthma patients have NEA, for which there is no specific treatment currently approved,*" said Garry A. Neil, MD, President and Chief Executive Officer, Avalo Therapeutics.

Phase 2 Trial
The PEAK trial (n=approximately 80) is a 12-week randomized, double-blind, placebo- controlled study to evaluate the safety and efficacy of AVTX-002 for the treatment of poorly controlled NEA (NCT05288504). The primary endpoint is the proportion of subjects who experience an asthma-related event. At baseline, subjects will be randomized to receive either AVTX-002 or placebo once monthly.

NEA
Asthma is a chronic disease of the lungs characterized by airway inflammation causing swelling and excess mucous production. Asthma is classified as eosinophilic or non- eosinophilic, with 50% of severe asthma cases related to NEA. Many patients with NEA respond suboptimally to standard asthma treatments, especially to inhaled corticosteroids. This can lead to a higher severity of disease and more difficult-to-control asthma, which can be life-threatening for some patients.

About Avalo Therapeutics
Avalo Therapeutics is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. The Company's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

For more information about Avalo, please visitwww.avalotx.com.

Forward-Looking Statements
This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts.

Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Avalo's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the future financial and operational outlook; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: Avalo's cash position and the potential need for it to raise additional capital; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel, including as a result of recent management changes; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and tensions in Ukraine; and those other risks detailed in Avalo's filings with the SEC. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

For media and investor inquiries

Christopher Sullivan, CFO
Avalo Therapeutics, Inc.
ir@avalotx.com
410-803-6793

or

Chris Brinzey
ICR Westwicke
Chris.brinzey@westwicke.com
339-970-2843

Exhibit 99.2

Avalo Therapeutics, Inc.

(AVTX)

Corporate Presentation

May 2022

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Forward-Looking Statements

This presentation may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond the control of Avalo Therapeutics, Inc. ("Avalo" or the "Company"), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; and other statements that are not historical.

These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel, including as a result of recent management changes; regulatory risks; Avalo's cash position and the potential need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; and those other risks detailed in Avalo's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

Experienced Management Team

Decades of successful leadership, product development, commercialization in pharma and biotech

Garry A. Neil, MD
President, Chief Executive Officer*

Chris Sullivan
Chief Financial Officer

Lisa Hegg, PhD
SVP, Program Management and Corporate Infrastructure

Colleen Matkowski
SVP, Global Regulatory Affairs and Quality Assurance

Scott White, MD
VP, Clinical Development

Dino C. Miano, PhD
SVP, CMC and Technical Operations

*Presenter

Avalo Therapeutics (AVTX)

- ✓ Focused portfolio emphasizing high value "first in class" immunology biologics
- ✓ AVTX-002 (anti-LIGHT mAb[1]) POC[2] in COVID-19 ARDS[3] with Fast Track and IBD[4]; NEA[5] PEAK[6] trial underway - phase 2 data 4Q22
- ✓ Pivotal LADDER[7] trial data for RPDD[8] CDG[9] program (AVTX-803) 4Q22

[1]mAb: monoclonal antibody; [2]POC: Proof of concept studies; [3]COVID-19 ARDS: SARS-COV2 associated acute respiratory distress syndrome (ARDS); [4]IBD: Inflammatory bowel disease; [5]NEA: Non-eosinophilic asthma; [6]PEAK trial: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX-002 for the Treatment of **P**oorly Controlled Non-**E**osinophilic **A**sthma **K**; [7]LADDER trial: A Phase 3, Randomized, Double-blind, Two-period, Crossover, Withdrawal Study to Assess the Efficacy and Safety of AVTX-803 in Subjects with **L**eukocyte **A**dhesion **D**eficiency Type II (LA**D** II) **ER**; [8]RPDD: Rare pediatric disease designation; [9]CDG: Congenital disorder of glycosylation

Avalo 2022 Corporate Highlights

New management team: Experienced experts who know the pipeline and people

Drive value for shareholders: Allocate capital to most promising programs

- Focus on highest value indications for promising novel biologics: AVTX-002 and AVTX-007
- Advance pivotal RPDD CDG programs: AVTX-803 and AVTX-801
- Out-license/divest non-strategic assets: AVTX-006

Emphasize:

- ✓ Rigorous scientific studies
- ✓ Operational excellence
- ✓ Strategic partnerships

Clinical-Stage Pipeline

Program	Mechanism of Action	Lead Indication	Designation	Clinical Development Stage			Anticipated Milestone
				Phase 1	Phase 2	Phase 3/Pivotal	
Immunology							
AVTX-002	Anti-LIGHT mAb	NEA	–				Phase 2 Top-line Data 4Q 2022
		Inflammatory bowel disease	–				*
		COVID-19 ARDS	Fast Track				**
AVTX-007	Anti-IL-18 mAb	Still's disease	–				‡
Rare Genetic Diseases							
AVTX-803	L-Fucose replacement	LAD II (SLC35C1-CDG)	ODD RPDD Fast Track				Pivotal Trial Data 4Q 2022
AVTX-801	D- Galactose replacement	PGM1-CDG					Pivotal Trial Data 2023‡‡

* The Company is considering a possible randomized, double-blind, placebo-controlled clinical trial in moderate-to-severe refractory patients with IBD

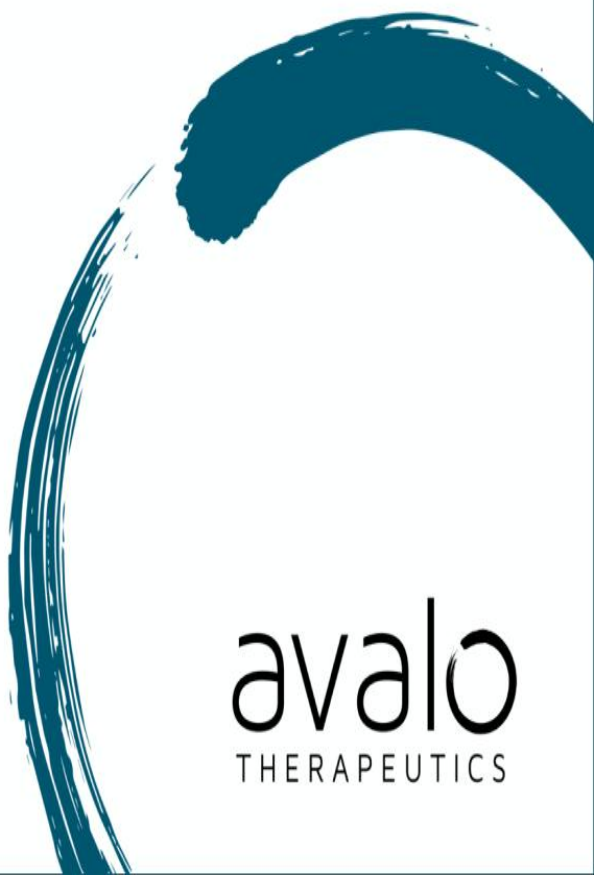
** Further development of AVTX-002 for treatment of COVID-19 ARDS is currently dependent on third party funding

‡ Management is currently reviewing preliminary data and path forward related to this indication; updates will be forthcoming upon finalization of the review

‡‡ This study is sponsored by a third party; currently working with study sponsor to refine milestone timing

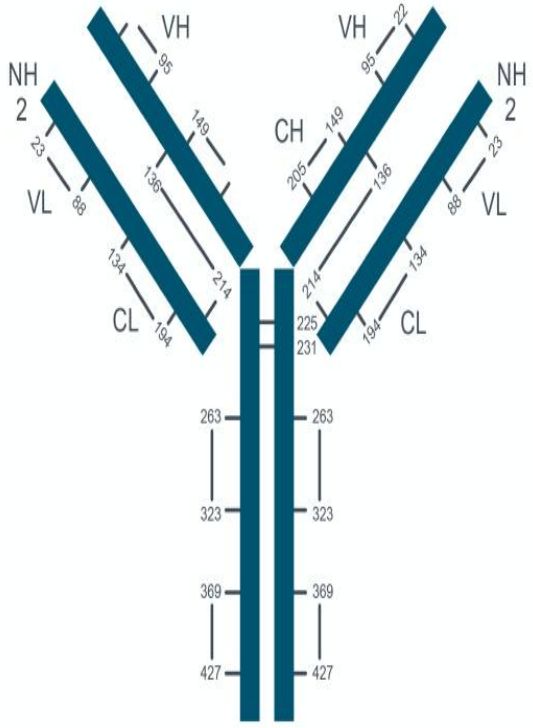
ARDS, acute respiratory distress syndrome; CDG, congenital disorder of glycosylation; IL, interleukin; LAD, leukocyte adhesion deficiency; mAb, monoclonal antibody; NEA, non-eosinophilic asthma; ODD, orphan drug designation; PGM1, phosphoglucomutase 1; RPDD, rare pediatric disease designation, Inflammatory bowel disease (IBD)

AVTX-002 (Anti-LIGHT mAb)



AVTX-002: First-in-class anti-LIGHT (TNFSF14) mAb

- Fully human monoclonal antibody (mAb) to LIGHT
- POC in 2 indications: COVID-19 ARDS & IBD[1]
- Currently in phase 2 for non-eosinophilic asthma (NEA)



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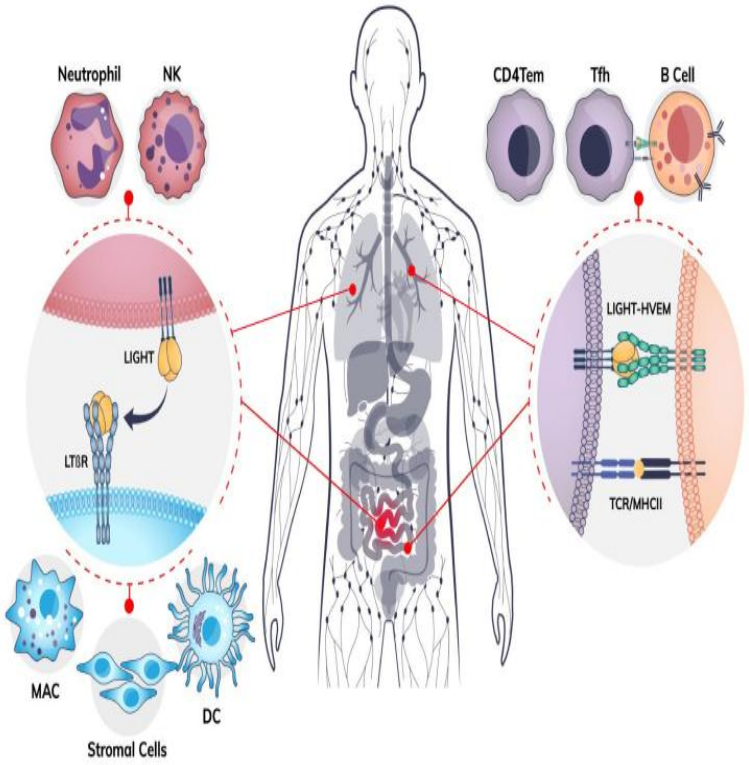
[1]Inflammatory Bowel Disease (IBD)

LIGHT is a Key Driver of Acute & Chronic Inflammation

- LIGHT/TNFSF14 is an immunoregulatory cytokine
- Critical for neutrophil, NK, T and B cell function
- 2 primary receptors: LTβR, HVEM receptors
- Pivotal role in lung, GI tract, & other tissues[1]
- Reducing LIGHT can moderate immune dysregulation in many acute and chronic inflammatory disorders

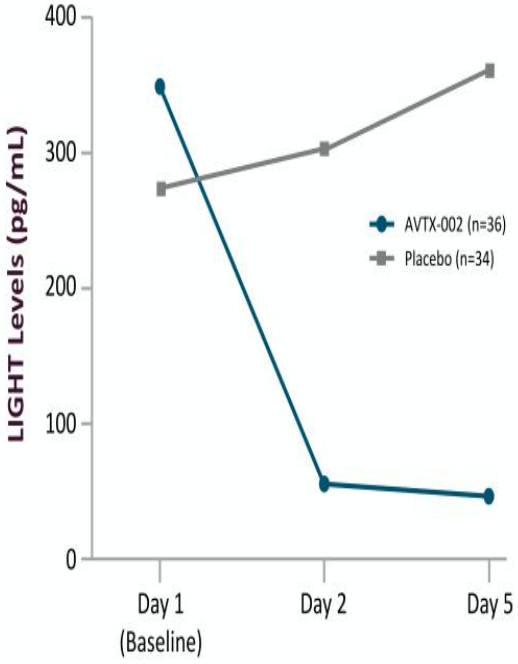


1. Ware, C., Croft, M., and Neil, G. Manuscript in preparation

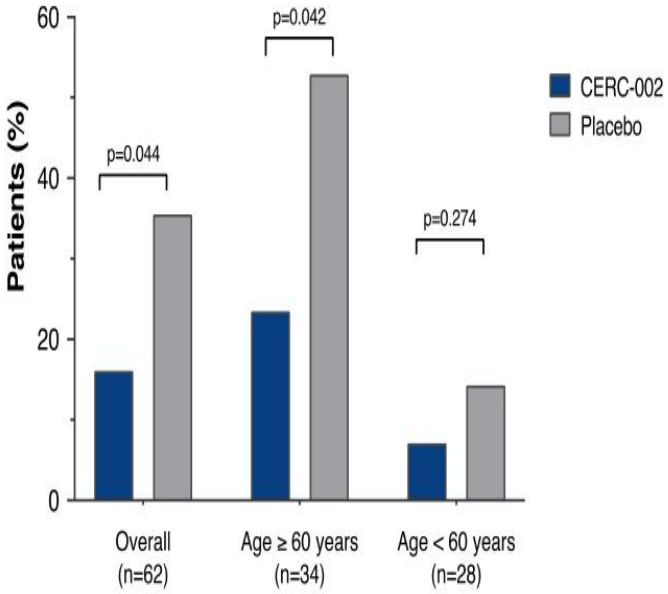
CD4Tem, effector-memory T cells; DC, dendritic cell; MAC, macrophage; NK, natural killer cell; Tfh, T follicular helper cells

AVTX-002 Significantly Reduced Respiratory Failure and Mortality in Phase 2 POC COVID-19 ARDS Study

LIGHT Levels (pg/mL) Over Treatment Period



Percentage of Patients with Respiratory Failure and/or Death by Day 28



Perlin, D. S. *et al.* Randomized, double-blind, controlled trial of human anti-LIGHT monoclonal antibody in COVID-19 acute respiratory distress syndrome. *J Clin Invest* (2021) doi:10.1172/jci153173.

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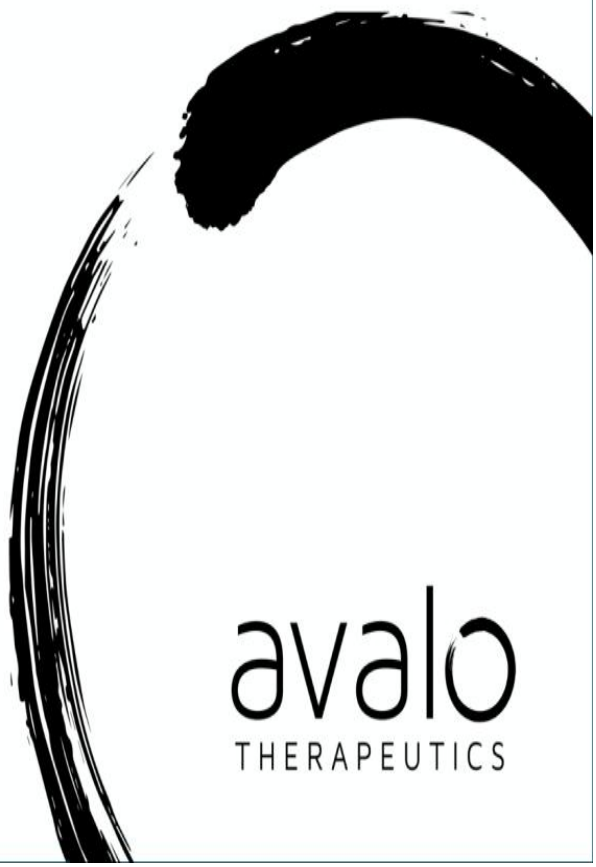
AVTX-002 POC in COVID-19 ARDS

- A single dose rapidly reduced serum free-LIGHT levels by ≃ 85%[1]
- Well-tolerated; no increase in serious adverse events vs placebo
- Evidence of clinically important anti-inflammatory effect in the lung
- Granted Fast Track Designation by FDA
- Potential for benefit in other causes of ARDS, and other lung inflammation

1. Perlin DS et al. Randomized, double-blind, controlled trial of human anti-LIGHT monoclonal antibody in COVID-19 acute respiratory distress syndrome

AVTX-002

Non-Eosinophilic Asthma (NEA)



Non-Eosinophilic Asthma (NEA)

Patient Population	• US prevalence of asthma ≃ 25M[1] • NEA accounts for ≃ 47% of asthma[2,3] • 50% of patients with asthma remain controlled[4]
Signs and Symptoms[4]	• Typical asthma symptoms; often more severe/resistant to treatment[5] • Associated with smoking, pollution, infections, obesity[5]
Treatment Approach[4]	• Standard therapies for asthma; many NEA patients remain uncontrolled[6,7] • Currently no approved targeted therapies for NEA
Rationale for AVTX-002	• Sputum LIGHT levels negatively associated with lung function (FEV_1 and FVC) in asthma[8,9] • Higher LIGHT levels in sputum in asthma patients with neutrophilia[8] • Neutrophils have high, pre-formed LIGHT levels[10]

1. Asthma and Allergy Foundation of America. Asthma facts and figures. https://www.aafa.org/asthma-facts/. Accessed January 3, 2022. 2. McGrath KW et al. *Am J Resp Crit Care Med.* 2012;185(6):612-619. 3. Jiang Y et al. *Allergy Asthma Clin Immunol.* 2021;17(1):45. 4. Centers for Disease Control and Prevention. AsthmaStats: Uncontrolled asthma among adults, 2016. https://www.cdc.gov/asthma/asthma_stats/uncontrolled-asthma-adults.htm. Accessed January 3, 2022.
5. Carr, T. F., Zeki, A. A. & Kraft, M. Eosinophilic and Noneosinophilic Asthma. *Am J Resp Crit Care* **197**, 22–37 (2017). 6. Esteban-Gorgojo I et al. *J Asthma Allergy.* 2018;11:267-281. 7. ClearView Healthcare Partners Analysis, June 2021. 8. Hastie AT et al. *J All… Immunol.* 2010;125(5):1028-1036. 9. Romeo J et al. *J Allergy Clin Immunol.* 2013;131(2 Suppl):AB203. Abstract 725. 10. Rørvig et al *J Leukocyte Biol* **94**, 711–721 (2013).

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AVTX-002 for Treatment of NEA: PEAK Trial Design

Trial Design

Multicenter, Phase 2 Trial of AVTX-002 in patients with NEA

Key Inclusion Criteria

- Poorly controlled asthma on LABA* and ICS†
- Exacerbation within 1 year previously
- Blood eosinophil count <300 cells/µL

Estimated Enrollment: n=80

AVTX-002 8 mg/kg (max 600 mg) q4wks (n=40)

14 weeks

- Discontinue LABA at Week 2
- Reduce ICS at Week 4 by 50%
- Discontinue ICS at Week 6

Placebo (n=40)

Primary Endpoint

- Time to exacerbation

Key Secondary/Exploratory Endpoints

- Change in FEV_1‡ from baseline
- Proportion of patients with exacerbation
- Change in FeNO# from baseline
- Change in ACQ§ from baseline

Top-line Data Expected 4Q22

*LABA, long-acting beta-agonist; †ICS, inhaled corticosteroid; ‡FEV_1, forced expiratory volume in 1 second; #FeNO, fractional exhaled nitric oxide; §ACQ, asthma control questionnaire.

Trial Design Performed With Dupilumab (Demonstrated Kaplan-Meier Curve Difference in Time to Exacerbation)

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Efficacy Signal Observed in Crohn's Disease Phase 1B Study

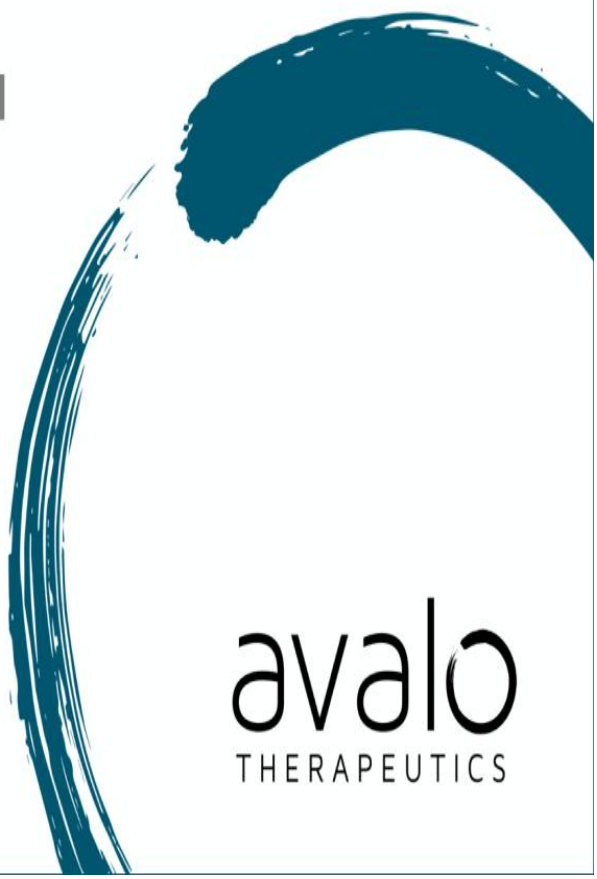
- Open-label, uncontrolled study in patients with moderate-to-severe Crohn's disease who previously failed anti-TNFα mAb[1] and other biologics
- Rapid reduction in serum free LIGHT levels
- Well-tolerated: no drug-related serious adverse events observed
- Clinically meaningful mucosal healing signal observed in preliminary analysis
  - 3 out of 7 patients demonstrated evidence of mucosal healing as determined by colonoscopy and adjudicated by a central reader with one patient achieving remission in preliminary analysis[2]
- Randomized placebo-controlled trial in ulcerative colitis under evaluation

[1]TNFα, tumor necrosis factor alpha; mAb, monoclonal antibody; [1]SES-CD, Simple Endoscopic Score for Crohn's Disease

[2]Final analysis of colonoscopy (SES-CD) scores, symptom scores and biomarkers ongoing expected in 2Q22

AVTX-803

Leukocyte Adhesion Deficiency Type II (LAD II, also known as SLC35C1-CDG)



AVTX-803: Leukocyte Adhesion Disorders (LAD II)

LAD Type II: Absence of sialyl Lewis X of E-selectin (*SLC35C1* mutation)

Overview

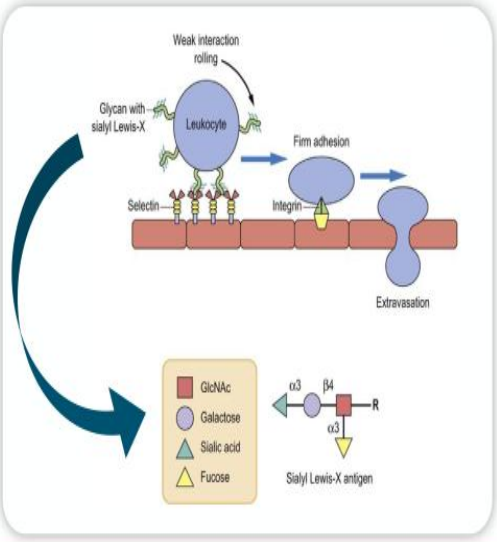
Patient Population
- Ultra-orphan disease: worldwide prevalence ~10-20 pt
- Nonfunctional GDP-fucose transporter with decreased fucosylation
- Absence of sialyl Lewis X (CD15a) expression

Signs and Symptoms
- Facial dysmorphism/growth & cognitive impairment
- Recurrent bacterial infections due to neutrophil dysfunction

Diagnosis/ Evaluation
- Flow cytometry for sialyl Lewis X (CD15a) expression
- Leukocytosis/neutrophil function assay
- H antigen expression (for pharmacodynamic effect)

Treatment
- Currently no FDA-approved treatment; patients use OTC fucose
- AVTX-803 granted orphan drug, Fast Track & Rare Pediatric Disease designations

LAD II (SLC35C1-CDG) Pathophysiology



- Type II (LAD II) caused by LOF mutation in *SLC35C1* gene resulting in the inability to fucosylate certain critical proteins
- Absence of sialyl Lewis X results in neutrophil dysfunction

AVTX-803 is an oral formulation of L-fucose that enhances fucosylation of proteins in the absence of a functioning GDP-fucose transporter, partially restoring protein function

AVTX-803 (L-fucose) for LAD II (SLC35C1-CDG): LADDER Trial Design

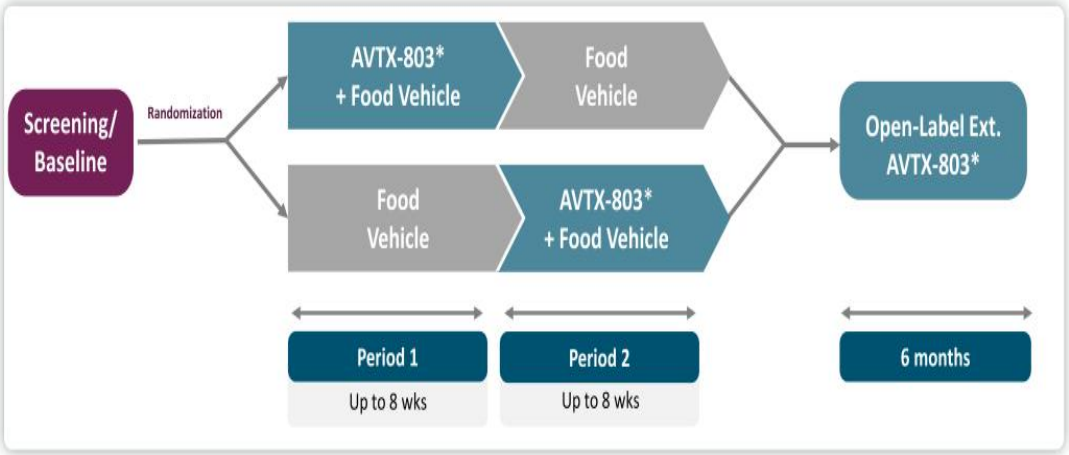
Trial Design

Single-Center (US), Double-Blind (plus Open-Label Extension) Pivotal Trial of AVTX-803 in patients with LAD II (SLC35C1-CDG)

Key Inclusion Criteria

- Known *SLC35C1* mutation
- Previous known response to L-fucose

Estimated Enrollment: n=2



Primary Endpoint

- Restoration of sialyl Lewis X biomarker

Key Secondary/Exploratory Endpoints

- Leukocyte function assay
- Neutrophil counts

Top-line pivotal data expected 4Q22

*100-300 mg/kg up to 5x/d based on clinical response

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Clinical-Stage Pipeline

Program	Mechanism of Action	Lead Indication	Designation	Clinical Development Stage	Anticipated Milestone
Immunology					
AVTX-002	Anti-LIGHT mAb	NEA	–	Phase 2	Phase 2 Top-line Data 4Q 2022
		Inflammatory bowel disease	–	Phase 2	*
		COVID-19 ARDS	Fast Track	Phase 2	**
AVTX-007	Anti-IL-18 mAb	Still's disease	–	Phase 1	‡
Rare Genetic Diseases					
AVTX-803	L-Fucose replacement	LAD II (SLC35C1-CDG)	ODD RPDD Fast Track	Phase 2	Pivotal Trial Data 4Q 2022
AVTX-801	D- Galactose replacement	PGM1-CDG		Phase 2	Pivotal Trial Data 2023‡‡

* The Company is considering a possible randomized, double-blind, placebo-controlled clinical trial in moderate-to-severe refractory patients with IBD

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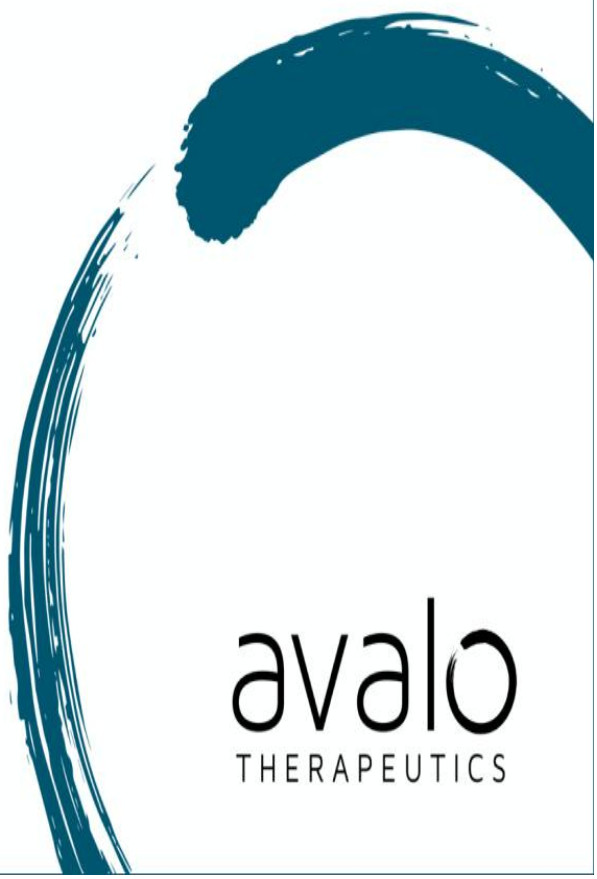
Finance Update



Financial & Investor Information

Key Financial Highlights

NASDAQ: AVTX

The following data is as of March 31, 2022:

- Cash – $38.5M*
- Outstanding common shares – 112.8M
- Fully diluted shares – 136M
- Average daily trading volume – 0.5M

** Preliminary unaudited cash balance as of April 30, 2022 is $32M*

2022: A Transformational Year for Avalo

New Management Team and Pipeline Focus

Multiple Meaningful Clinical Catalysts

- AVTX-002 NEA data from PEAK trial (80-patient Phase 2 trial) in 4Q22
- AVTX-803 LAD II (SLC35C1-CDG) pivotal data from LADDER trial in 4Q22

Business Development Opportunities

- AVTX-006 potential for out-licensing/divestiture
- AVTX-002 and AVTX-007 evaluate additional strategic opportunities to accelerate development and indication expansion