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 16, 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 August 16, 2022, Avalo Therapeutics, Inc. ("the Company") posted on its website an updated investor presentation (the "Investor Presentation"). The Investor Presentation reflects refinement to the Company's strategy by focusing on the LIGHT-signaling network, unveiling of the Company's preclinical BTLA agonist fusion protein and updating of certain financial information for second quarter results. The Investor Presentation will be used from time to time in meetings with investors. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	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: August 16, 2022

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

EX-99.1

Avalo Therapeutics, Inc.

(AVTX)

Corporate Presentation

August 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; Avalo's ability to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market; Avalo's cash position and the potential need for it to raise additional capital; reliance on key personnel, including as a result of recent management and Board changes; regulatory risks; 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.

Avalo Therapeutics (AVTX)

- ✓ Portfolio emphasizing high value "first in class" biologics focused on dysregulated inflammation via the LIGHT-signaling network
- ✓ AVTX-002 (anti-LIGHT mAb) POC completed in COVID-19 ARDS and IBD; Non-Eosinophilic Asthma PEAK trial underway – Phase 2 topline data 1H23
- ✓ BTLA Agonist Fusion Protein (AVTX-008) – IND 2024
- ✓ Exclusive consulting arrangement with Carl Ware, Ph.D., Sanford Burnham Prebys Medical Discovery Institute (discoverer of the LIGHT-signaling network)

LIGHT, **L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes; **mAb,** monoclonal antibody; **NEA,** non-eosinophilic asthma; **POC,** Proof of concept studies; **COVID-19 ARDS,** SARS-COV2 associated acute respiratory distress syndrome (ARDS); **IBD,** Inflammatory bowel disease; **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**; **BTLA**, B and T Lymphocyte Attenuator, Ig superfamily checkpoint

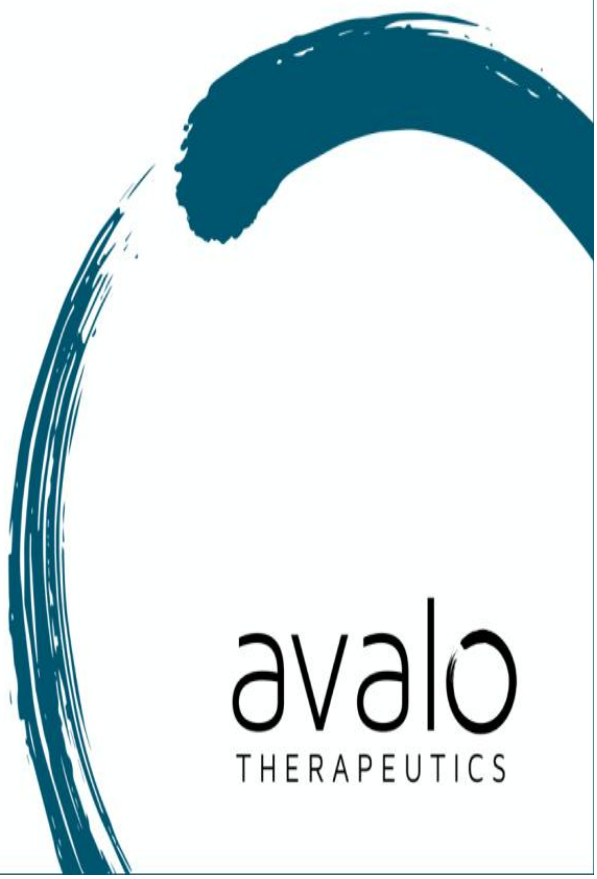
Pipeline

Program	Mechanism of Action	Indication	Designation	Development Stage	Anticipated Milestone
Core Programs: Immune Dysregulation Disorders					
AVTX-002	Anti-LIGHT mAb	NEA	–	Phase 2	Phase 2 Top-line Data 1H 2023
		Crohn's Disease	–	Phase 2	*
		COVID-19 ARDS	Fast Track	Phase 2	*
AVTX-008	BTLA agonist fusion protein	Immunoregulatory disorders	–	Preclinical	IND 2024
Other					
AVTX-803	L-fucose replacement	LAD II (SLC35C1-CDG)	ODD RPDD Fast Track	Phase 3/Pivotal	Pivotal Trial Data 1H 2023
AVTX-007	Anti-IL-18 mAb	–	–	Phase 2	Out Licensed / Transferred

* The Company will assess the next stage of development for these indications as well as potentially others, upon or close to, data readout of the NEA trial.

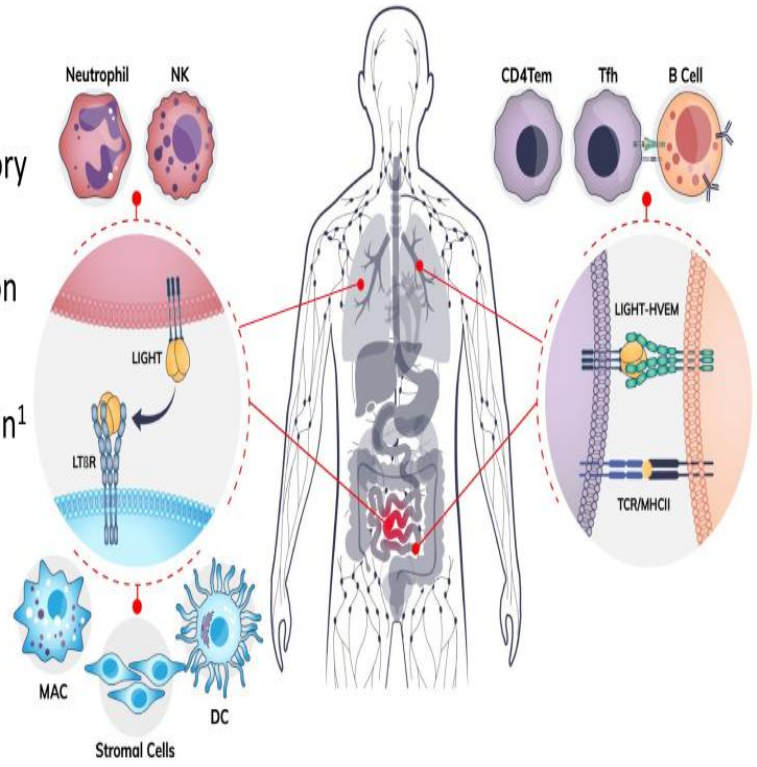
ARDS, acute respiratory distress syndrome; **BTLA,** B and T lymphocyte attenuator, Ig superfamily checkpoint; **CDG,** congenital disorder of glycosylation; **LAD,** leukocyte adhesion deficiency; **LIGHT,** Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes; **mAb,** monoclonal antibody; **NEA,** non-eosinophilic asthma; **ODD,** orphan drug designation; **RPDD,** rare pediatric disease designation; **IBD,** inflammatory bowel disease

AVTX-002 (Anti-LIGHT mAb)



LIGHT is a Key Driver of Acute & Chronic Inflammation

- Proinflammatory cytokine in the TNF super family
- Key component of a larger immunoregulatory network, including BTLA
- Critical for neutrophil, NK, T & B cell function
- 2 primary receptors: LTβR, HVEM
- Pivotal role in body "barriers": lung, gut, skin[1]
- Modulating LIGHT can moderate immune dysregulation in many acute and chronic inflammatory disorders

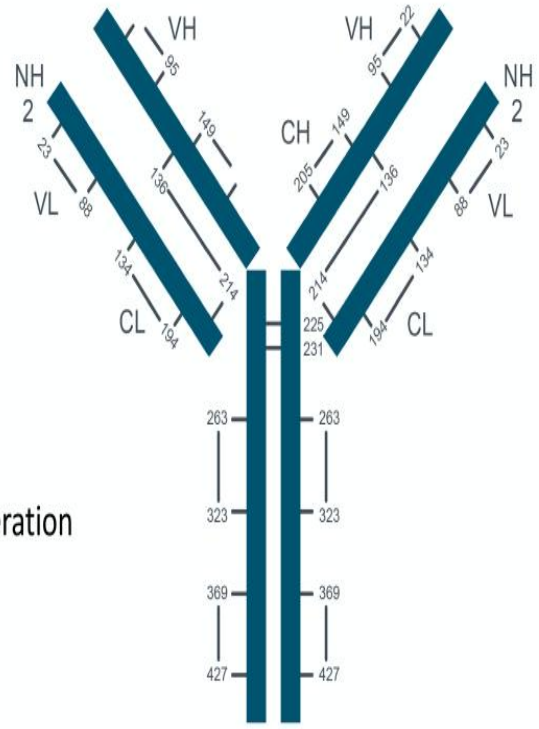


1. Ware, C., Croft, M., and Neil, G. *J.Exp Med.* 2022 Jul 4;219(7):e20220236. 10.1084/jem.20220236.

CD4Tem, CD4 effector-memory T cells; **DC,** dendritic cell; **HVEM,** herpes virus entry mediator; **LTβR;** Lymphotoxin beta receptor; **MAC,** macrophage; **NK,** natural killer cell; **Tfh,** T follicular helper cells; **TNF,** tumor necrosis factor

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

- Fully human monoclonal antibody to LIGHT
- CMC at 2,000 L scale; 6-month tox study near completion
- POC in 2 indications: COVID-19 ARDS & Crohn's Disease
- Currently in phase 2 for non-eosinophilic asthma
- Additional indications in immune dysregulation under consideration



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TNFSF14, tumor necrosis factor superfamily member 14

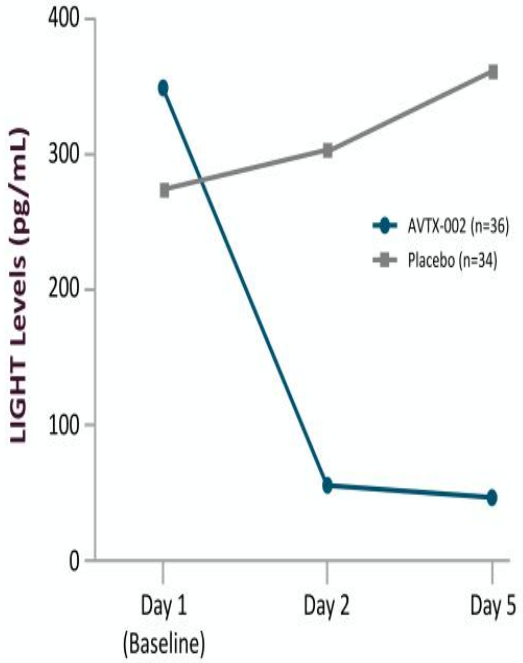
POC demonstrated in Phase II COVID-19 ARDS study

- Demonstrated target engagement: 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

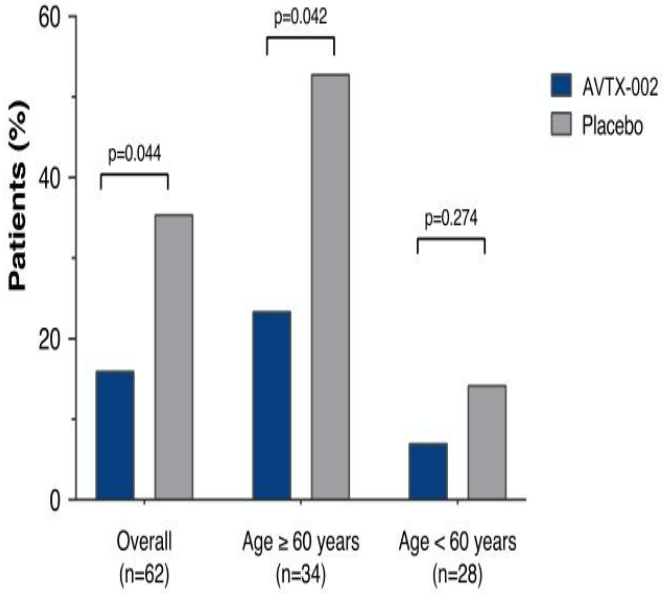
1. Perlin DS et al. Randomized, double-blind, controlled trial of human anti-LIGHT monoclonal antibody in COVID-19 acute respiratory distress syndrome. J. Clin. Invest. 2022

Significant Reduction in COVID-19 Induced Respiratory Failure and Mortality

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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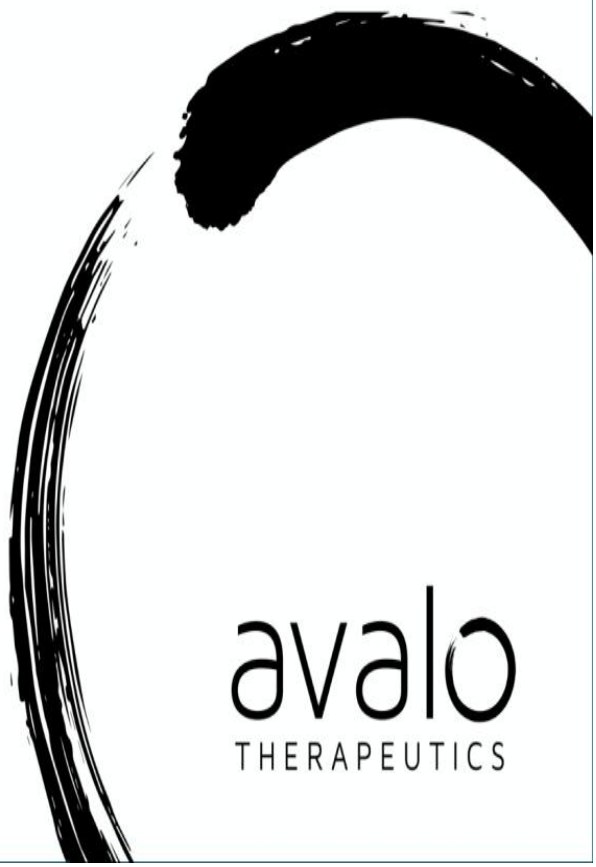
AVTX-002

Non-Eosinophilic Asthma (NEA)



Non-Eosinophilic Asthma (NEA)

Patient Population

- US prevalence of asthma ≃ 25M[1]
- NEA accounts for ≃ 47% of asthma[2,3]
- Majority of patients with asthma remain uncontrolled[4]
- Higher need in underserved populations

Signs and Symptoms[4]

- 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 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. [illegible] AT et al. *J Allergy Clin 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).

FEV, forced expiratory volume in 1 second; **FVC,** forced vital capacity

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AVTX-002 for Treatment of NEA: Phase 2 Trial Design

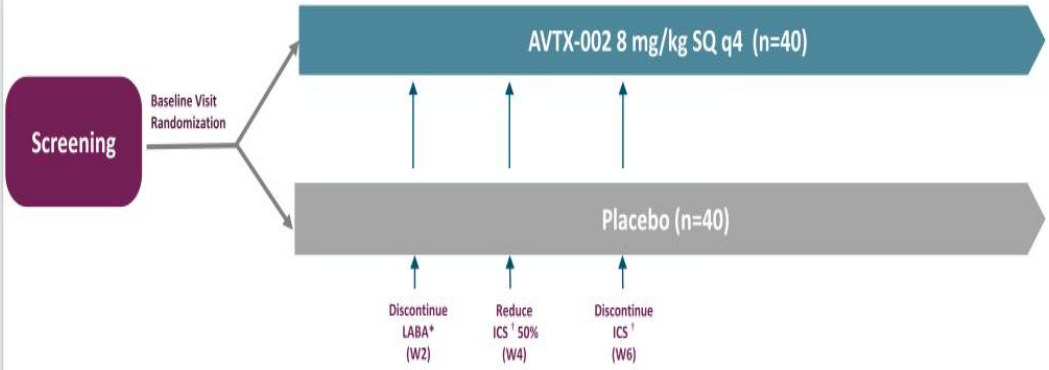
PEAK Trial

Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of AVTX-002 in patients with NEA

Key Inclusion Criteria

- Poorly controlled asthma on LABA and ICS
- Exacerbation in the last 24 months
- Blood eosinophil count <300 cells/µL

Estimated Enrollment (n=80)



Primary Endpoint

- Proportion of patients who experience an exacerbation of asthma defined as:
  - ≥6 additional reliever puffs of SABA‡ (compared to baseline) in a 24-hour period on 2 consecutive days or,
  - increase in ICS† dose ≥4 times than the dose at baseline or,
  - a decrease in peak flow of 30% or more (compared to baseline) on 2 consecutive days of treatment

Key Secondary/Exploratory Endpoints

- Change in FEV_1‡ from baseline
- Time to exacerbation
- Change in FeNO# from baseline
- Change in ACQ§ from baseline

Top-line pivotal data expected 1H23

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

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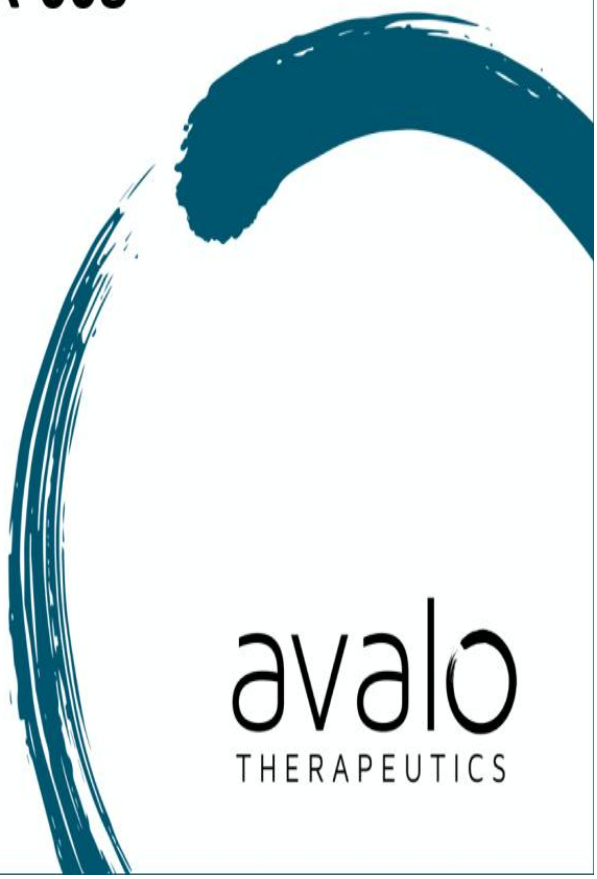
LIGHT Signaling Network & AVTX-008 (BTLA agonist fusion protein)



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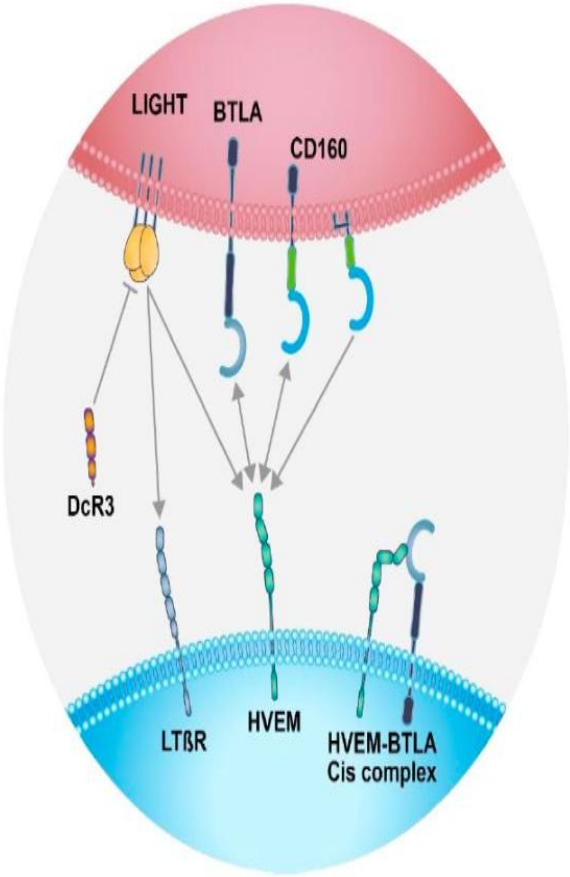
The LIGHT Signaling Network - A Key Immunoregulatory System



Arrow heads refer to mono and bidirectional signaling

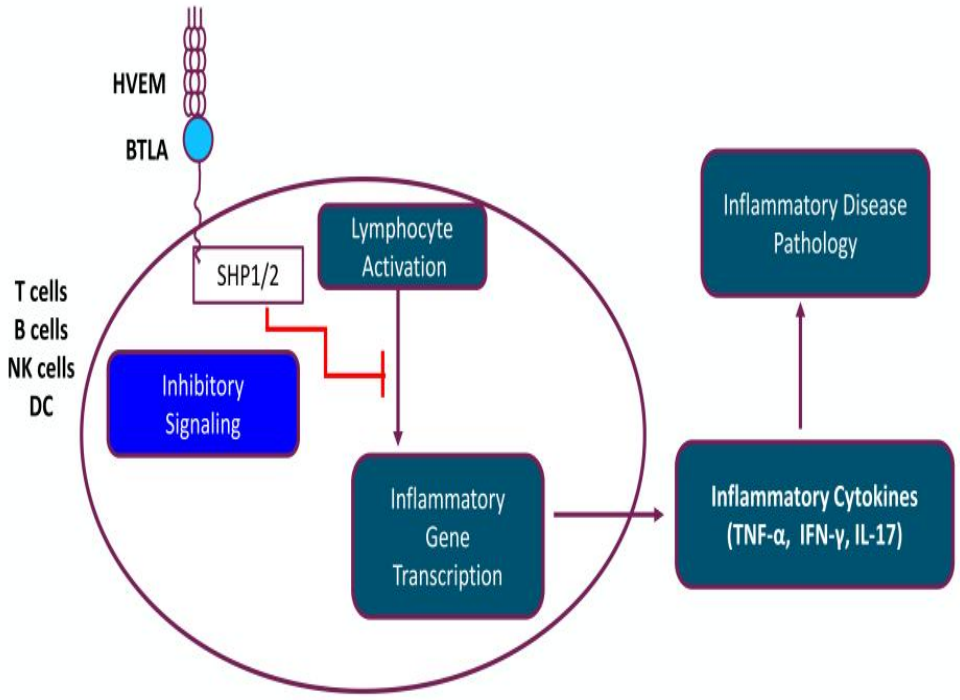
- BTLA - B and T lymphocyte attenuator (Ig superfamily checkpoint)
  - Co-expressed with HVEM in T and B cells
  - "Dampens" the immune response
- LIGHT activates HVEM
  - Inhibits BTLA signaling, allowing immune stimulation
- LIGHT activates LTβR
  - Activates dendritic cells, macrophages, stromal cells
  - Recruits lymphocytes
  - Stimulates antigen presentation & lymphoid organization
- DcR3 inhibits/regulates LIGHT
- CD160 competes with BTLA for HVEM
  - Stimulated immune activation by restricting inhibitory signaling in NK, CTL, Tfh
- BTLA and CD160 can activate HVEM (bidirectional signaling)

Ward-Kavanagh, et al Immunity 2016 Šedý et al Cold Spring Harb Perspect Biol 2014
Mintz & Cyster Immunol Rev 2020
Ware, C., Croft, M., and Neil, G. J.Exp Med. 2022 Jul 4;219(7):e20220236. 10.1084

DcR3, decoy receptor 3

AVTX-008 MOA is distinct from other autoimmune therapeutics*

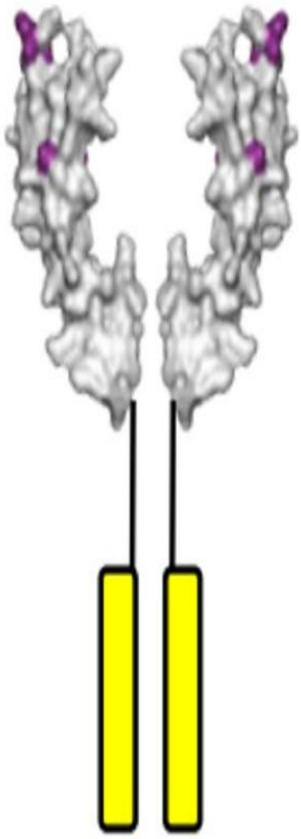
- Eliminates effector cells that mediate chronic autoimmune disease
- Activation of the BTLA inhibitory receptor by its ligand HVEM turns on SHP phosphatases limiting lymphocyte activation and inflammatory cytokine signaling



*(Orencia and Enbrel)

AVTX-008: BTLA Agonist Fusion Protein

- Bioengineered HVEM fusion protein
- Specific and high affinity agonist for BTLA
- Fully human
- IND expected 2024
- Target indications: immune dysregulation, SLE, GVHD



SLE, Systemic lupus erythematosus; **GVHD,** Graft versus host disease

Executive Summary, AVTX-008

Molecule	AVTX-008 Bioengineered HVEM, specific and high affinity agonist for BTLA B and T lymphocyte attenuator, an immune checkpoint
MOA	• Novel mechanism of action • Inhibits lymphocyte activation and effector cells through BTLA
Unmet Need	• Immunoregulatory disorders: Lupus, Crohn's Disease and non-responders to TNF inhibitors
Stage	• IND 2024
Clinical Advantages	• Inhibition of inflammatory cytokine production predicts efficacy in patients not responsive to anti-TNF therapy • Efficacy in murine lupus model excels compared to Abatacept • Reduced risk of anti-drug response • Proven modality of Fc fusion proteins: Orencia, Enbrel
Business Advantages	• First-in-class therapeutic • Excellent intellectual property coverage

World Class Scientific Advisor

- Carl Ware, PhD, Head Avalo SAB
- Director, infectious and Inflammatory Disease Center
- Professor, Immunity and Pathogenesis Program
- Directory, Laboratory of Molecular Immunology
- Discoverer of LIGHT signaling network

Sanford™ Burnham Prebys

SAB, Scientific Advisory Board

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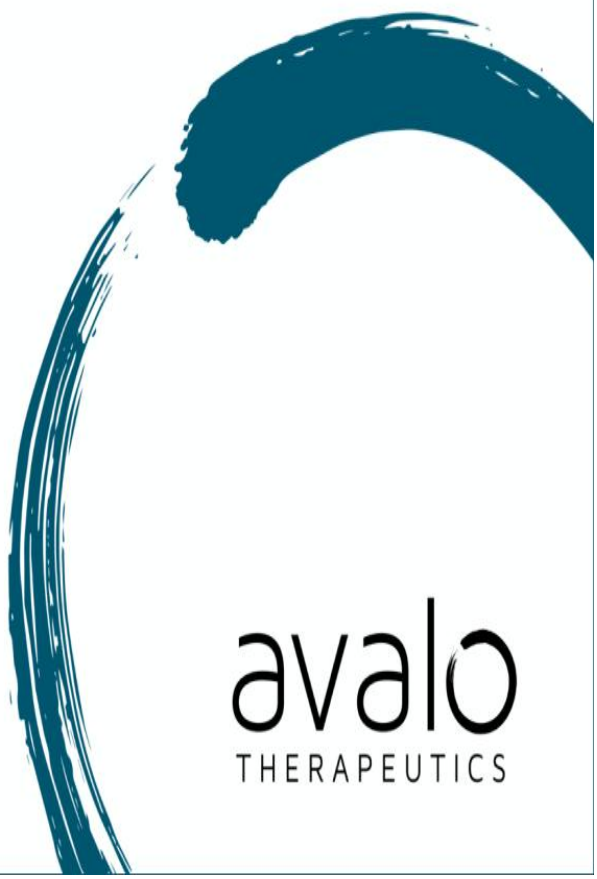
Finance Update



Financial & Investor Information

Key Financial Highlights

NASDAQ: AVTX

The following data is as of June 30, 2022:

- Cash – $11.2M; subsequently received approximately $15M in August related to the transfer of AVTX-007 to Apollo Therapeutics
- Outstanding common shares – 9.4M[1]
- Fully diluted shares – 11.3M[1]
- Average daily trading volume – 43K[1]

[1] *Retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022.*

Experienced Management Team

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

Garry A. Neil, MD
President, Chief Executive Officer

AstraZeneca

Johnson & Johnson

ARENA PHARMACEUTICALS

Chris Sullivan
Chief Financial Officer

SUCAMPO
The Science of Innovation

OpGen

EY

Lisa Hegg, PhD
SVP, Program Management and Corporate Infrastructure

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gsk
GlaxoSmithKline

Colleen Matkowski
SVP, Global Regulatory Affairs and Quality Assurance

Takeda

BIOMARIN

FDA

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

ALEXION

Scott White, MD
VP, Clinical Development

gsk
GlaxoSmithKline

INOVIO
POWERING DNA MEDICINES

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Avalo Therapeutics (AVTX)

- ✓ Portfolio emphasizing high value "first in class" biologics focused on dysregulated inflammation via the LIGHT-signaling network
- ✓ AVTX-002 (anti-LIGHT mAb) POC completed in COVID-19 ARDS and IBD; Non-Eosinophilic Asthma PEAK trial underway – Phase 2 topline data 1H23
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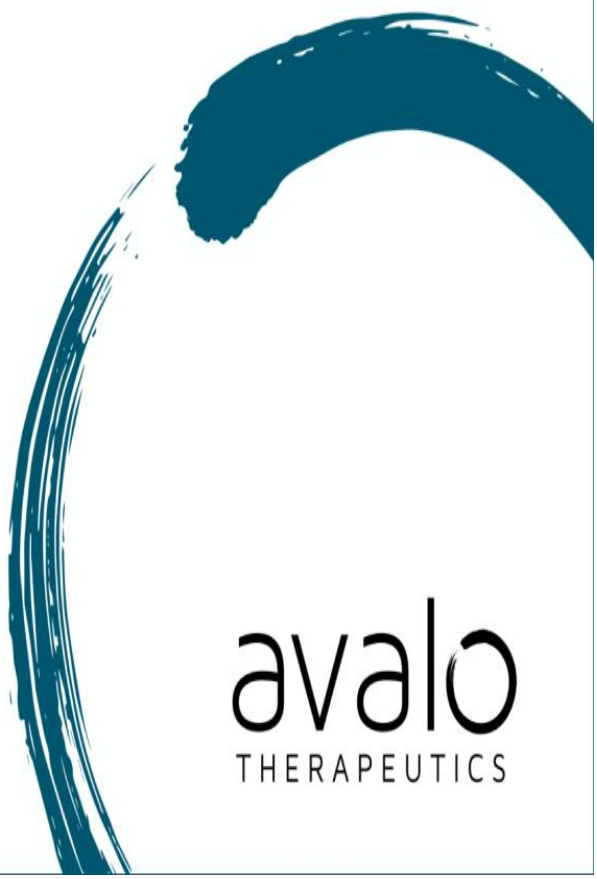
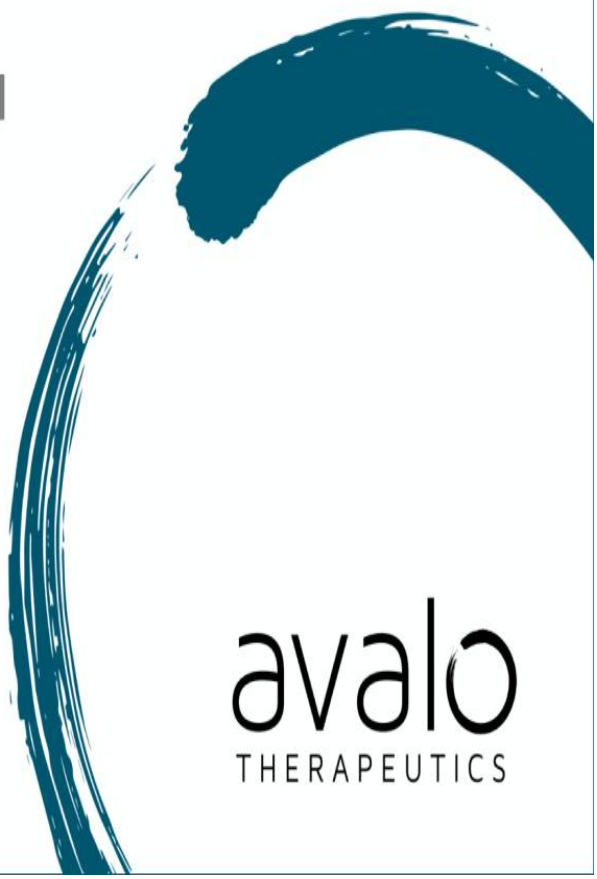
Appendix



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

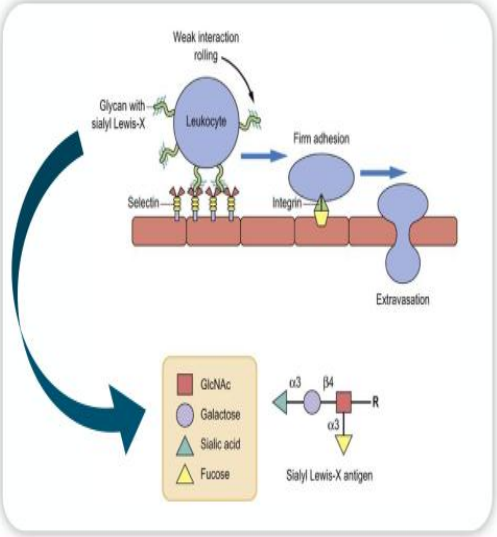
Patient Population
- Ultra-orphan disease: worldwide prevalence ~10-20 pt
- Nonfunctional GDP-fucose transporter with decreased fucosylation
- Absence of sialyl Lewis X (CD15a) expression

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): Pivotal Trial Design

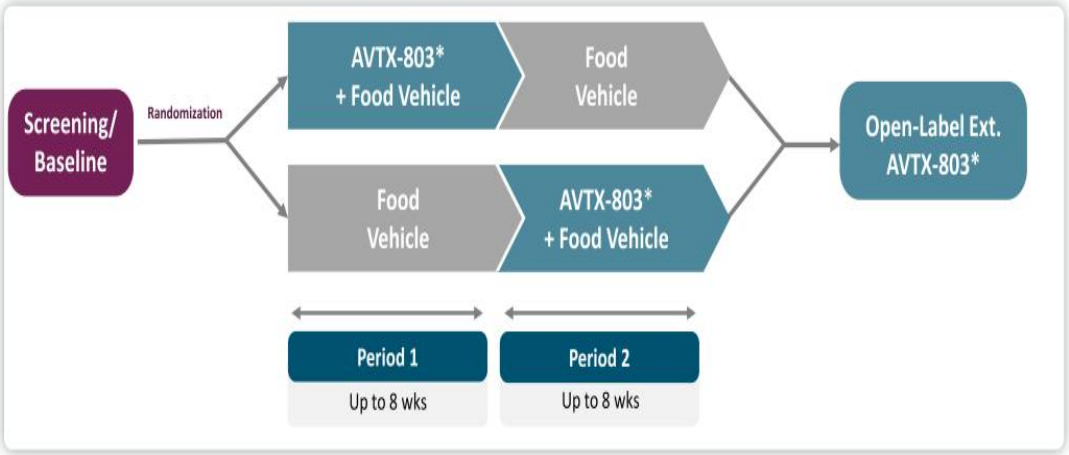
LADDER Trial Design

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 1H23

*100-340 mg/kg up to 5x/d based on clinical response