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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): June 20, 2025**

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

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**Delaware**

(State or other jurisdiction of incorporation)

**001-37590**  
(Commission File Number)

**45-0705648**  
(IRS Employer Identification No.)

**1500 Liberty Ridge Drive, Suite 321, Wayne, Pennsylvania 19087**  
(Address of principal executive offices) (Zip Code)

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

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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. ☐

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**Item 8.01 Other Events.**

On June 20, 2025, Avalo Therapeutics, Inc. 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. 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:

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Investor Presentation.</a>
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: June 20, 2025

By: /s/ Christopher Sullivan

Christopher Sullivan  
Chief Financial Officer

avalo  
THERAPEUTICS



One mission.

Advancing an inspired pipeline of novel IL-1 $\beta$  therapies  
focused on treating unmet medical needs.

**CORPORATE OVERVIEW**

JUNE 2025 | AVALO THERAPEUTICS, INC. (AVTX)

# 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 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: integration of AVTX-009 into our operations; drug development costs, timing of trial results and other risks, including reliance on investigators and enrollment of patients in clinical trials; the intended use of the proceeds from the private placement; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the war in Ukraine and the Middle East; and those other risks detailed in Avalo's filings with the Securities and Exchange Commission, available at [www.sec.gov](http://www.sec.gov). 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: Advancing the Next-Generation of IL-1 $\beta$ Inhibition for Immune Mediated Inflammatory Diseases



## Lead compound AVTX-009 (anti-IL-1 $\beta$ mAb) has the potential for best-in-class and best-in-disease profile in hidradenitis suppurativa (HS)

- Significant unmet need due to incomplete response and loss of response to current treatment
- Abbvie's lutikizumab (IL-1 $\alpha/\beta$ ) demonstrated comparable efficacy to market leaders and pipeline therapeutics, and in a refractory population that had failed anti-TNF therapy
- IL-1 $\beta$  (not IL-1 $\alpha$ ) is a dominant immunoregulator in HS, based on preclinical and clinical evidence<sup>1,2,3</sup>
- AVTX-009 has 15x higher affinity and a longer half-life than lutikizumab, potentially predictive of higher efficacy and less frequent dosing<sup>4</sup>

Phase 2 LOTUS trial  
in HS enrolling with  
topline data expected  
mid-2026

HS market is  
expected to grow to  
> \$10B by 2035<sup>5</sup>

AVTX-009 has  
the potential to treat  
additional immune-  
mediated inflammatory  
diseases

Expected cash runway  
into 2028



# Avalo Management Team

**A proven track record of successful leadership,**  
product development, and commercialization in pharma and biotech



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



**Mittie Doyle, MD**  
Chief Medical Officer



**Chris Sullivan**  
Chief Financial Officer



**Paul Varki**  
Chief Legal Officer



**Jennifer Riley**  
Chief Strategy Officer



**Colleen Matkowski**  
SVP, Global Regulatory Affairs,  
Quality Assurance



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



**Lisa Hegg, PhD**  
SVP, Program Management, Business  
Development & Corporate Infrastructure



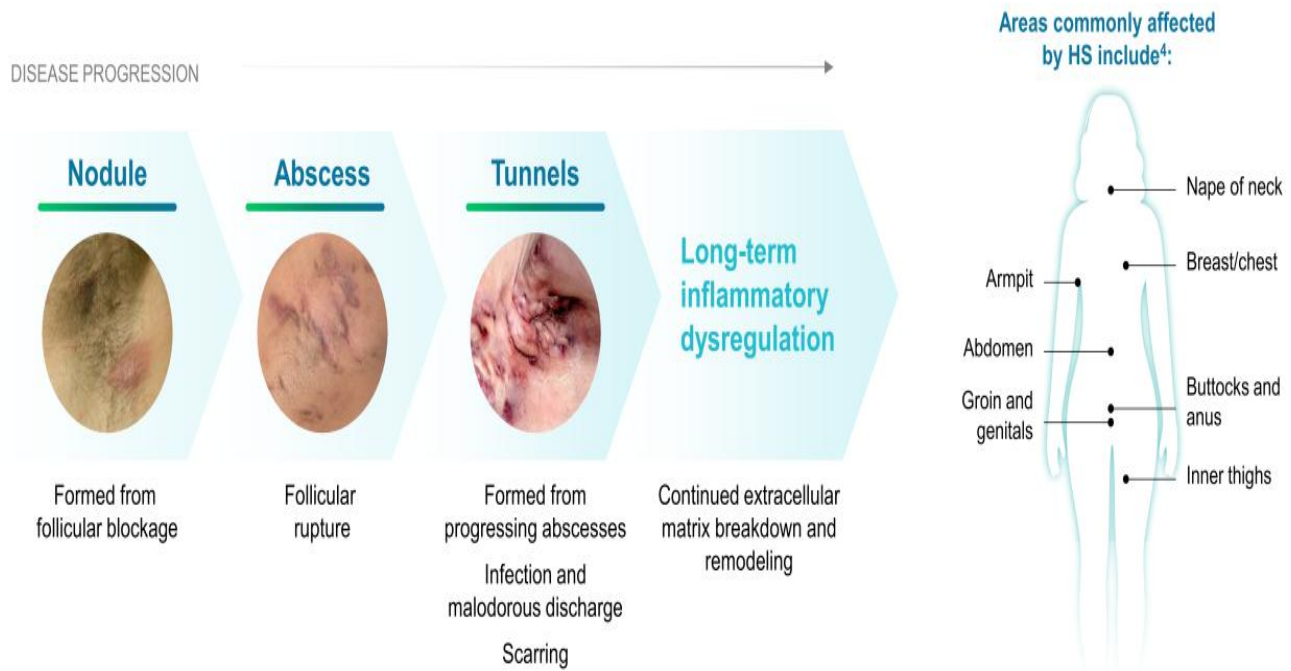


AVTX-009: Designed to Target the  
Inflammatory Driver of Hidradenitis  
Suppurativa (HS) to Address  
Significant Unmet Need



# Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction

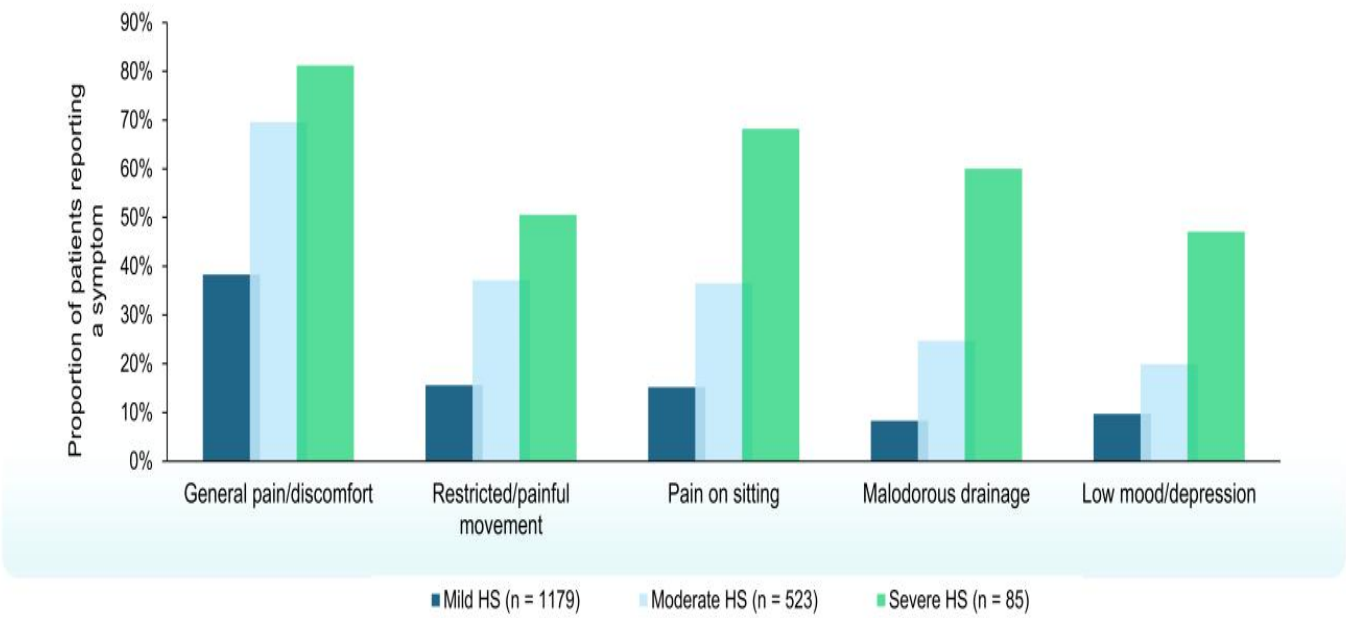
**HS is a chronic, often debilitating inflammatory skin disease** that causes painful lumps, abscesses, and tunnels to form under the skin



# Persistent Unmet Need in HS Due to Limited Efficacy of Current Anti-TNF and Anti-IL-17 Biologic Therapies

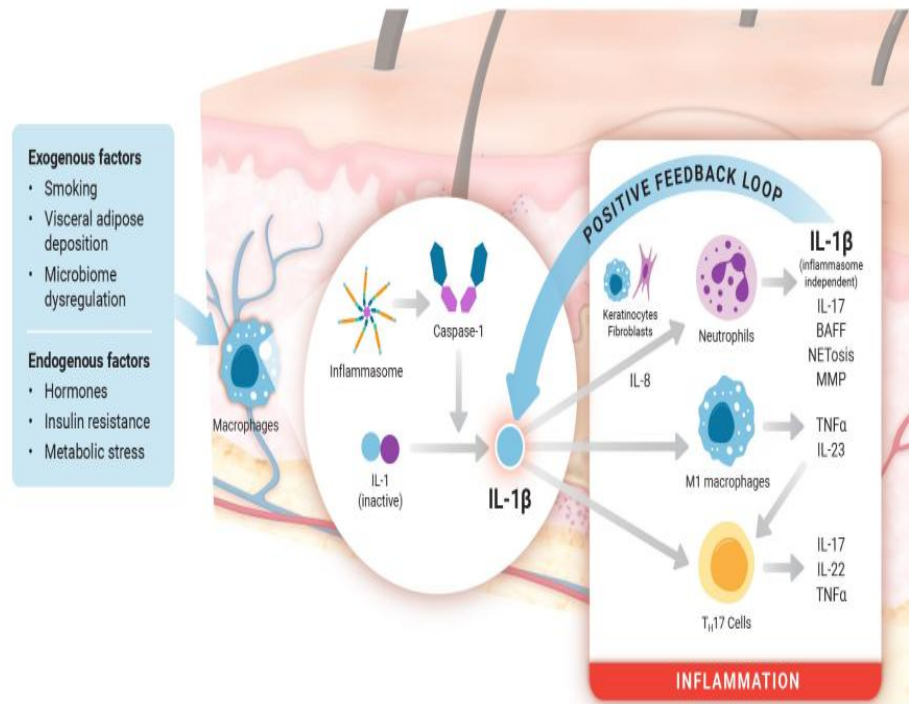
## Severe Impact on Quality of Life

A large proportion of patients still report significant and life-disrupting symptoms with existing treatment options<sup>1,2,a</sup>



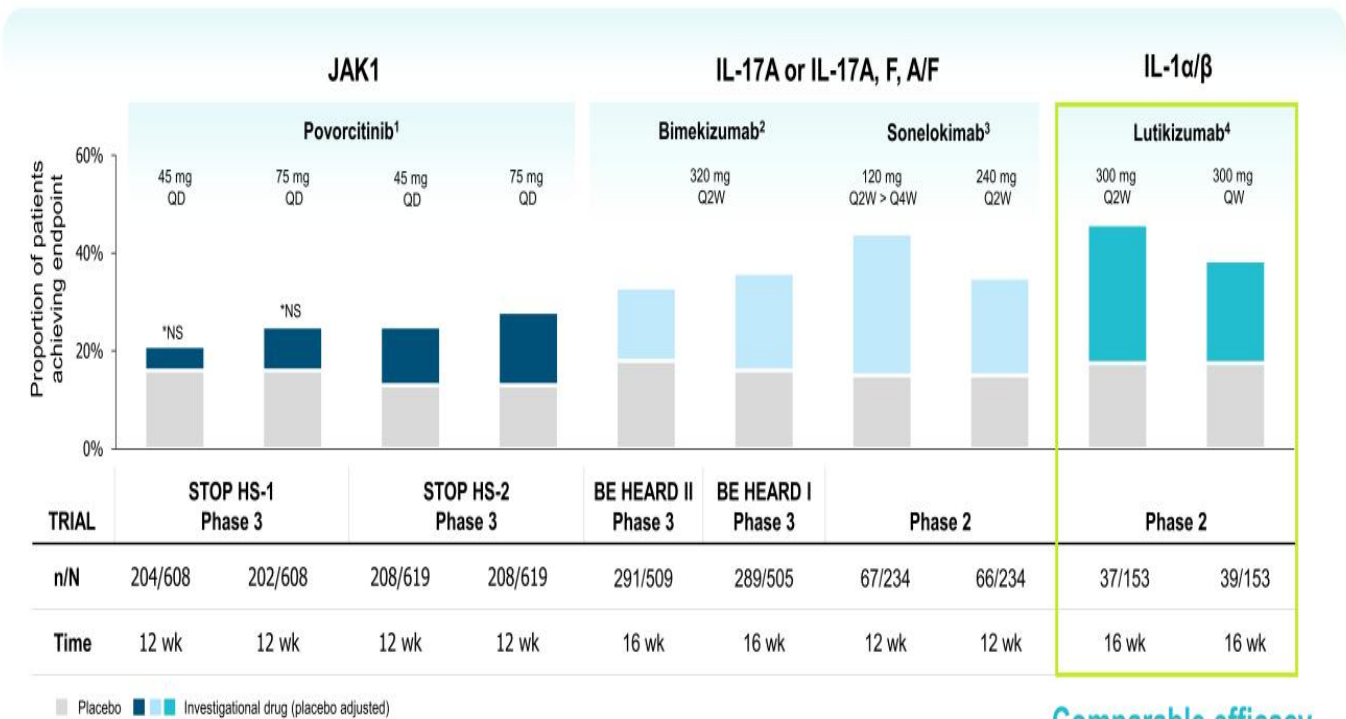
# IL-1 $\beta$ Dominates the Pathophysiology of HS

- IL-1 $\beta$  is a key driver of the inflammatory cascade that leads to the destruction of the pilosebaceous unit
- IL-1 $\beta$  gene expression is up to 100x increased in HS lesions compared to skin in healthy controls<sup>1,2</sup>
- IL-1 $\beta$  is upstream of IL-17 and TNF $\alpha$ , both major effectors of inflammation<sup>3</sup>
- Clinical benefit in HS has been observed with anti-IL-1 drugs<sup>4</sup>



# Phase 2 Lutikizumab Data Validates the Role for IL-1 in HS; Comparable Efficacy in a Refractory Population

## HiSCR75

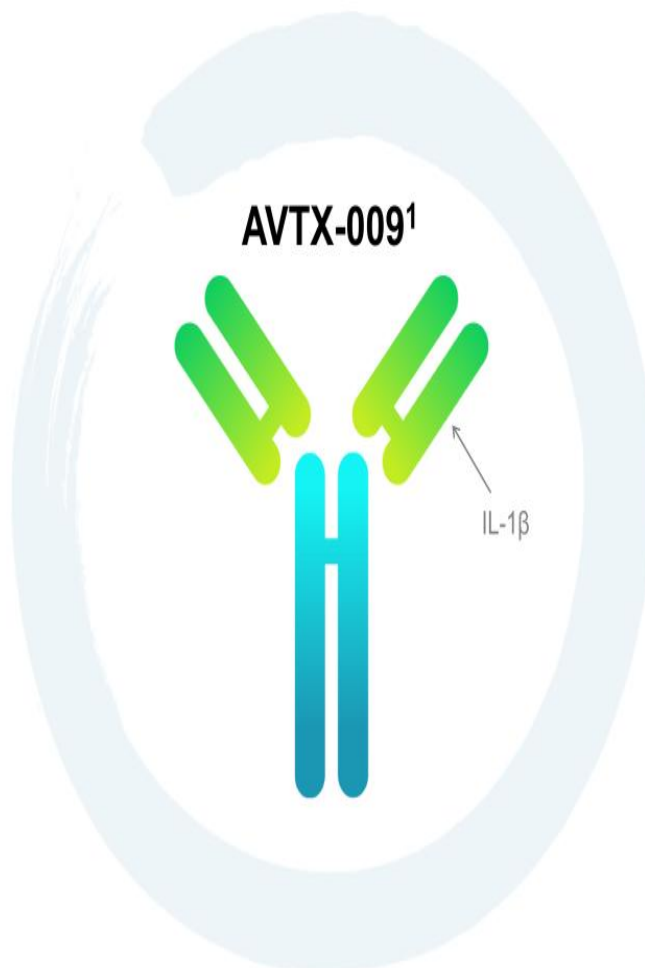


Comparable efficacy  
in a refractory population  
(71% Hurley stage III) that had  
already failed anti-TNF therapy

\*NS, not statistically significant  
HiSCR, hidradenitis suppurativa clinical response; IL, interleukin; JAK1, janus kinase 1; MOA, mechanism of action;  
TNF, tumor necrosis factor; wk, week; QD, daily; QW, weekly; Q2W, every other week; Q4W, ever 4 weeks.  
1. Incyte data presentation March 17, 2025; 2. Kimball AB, et al. *Lancet*. 2024;403(10443):2504-2519; 3. Kimball  
AB, Kirby B, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA; 4. Kimball  
AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

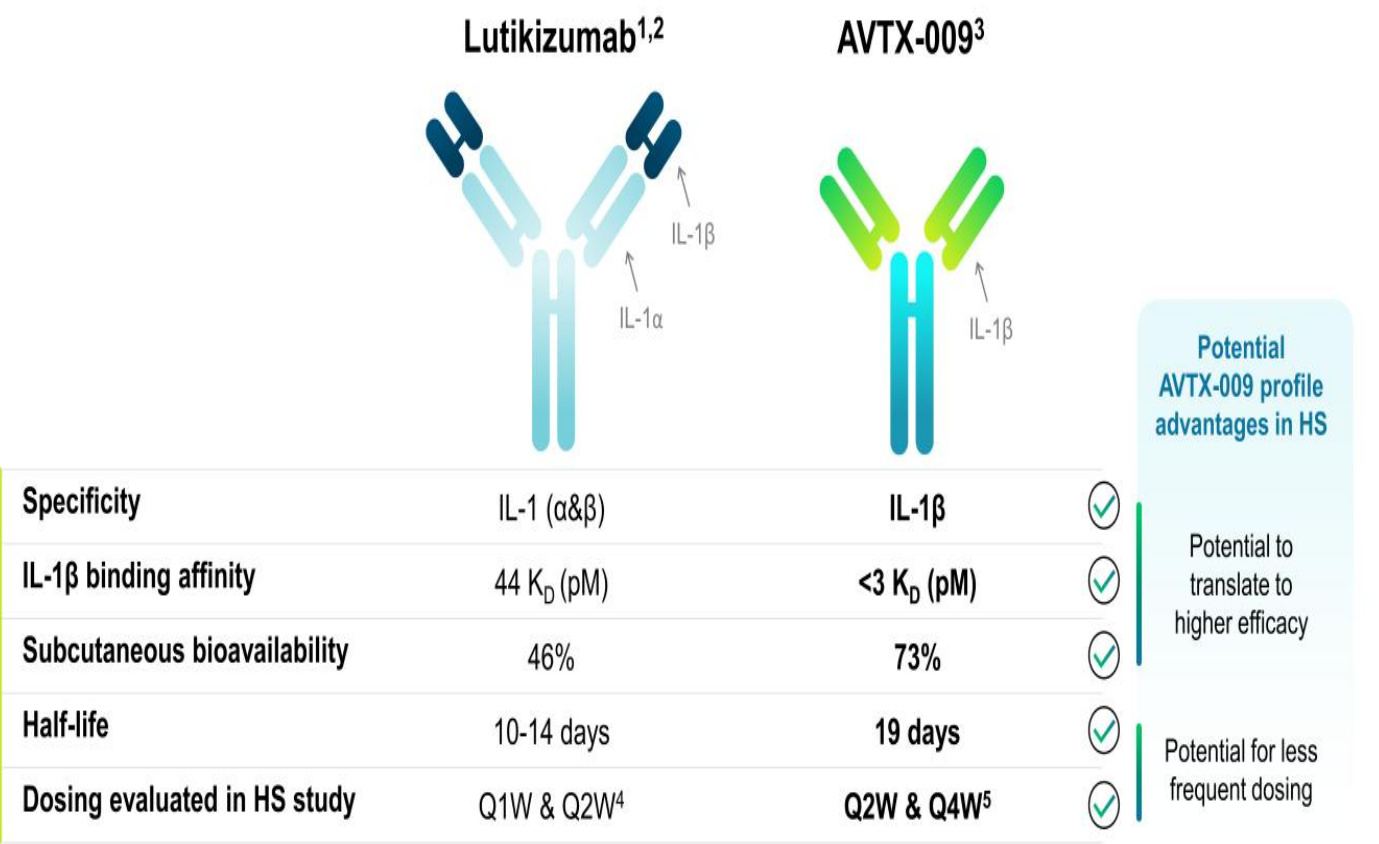
# AVTX-009 Is A Highly Potent, Specific Inhibitor of IL-1 $\beta$

- Clinical experience
  - 245 patients studied in phase 1 and phase 2 trials<sup>2,3-6</sup>
  - Significant and rapid lowering of inflammatory biomarkers after a single dose of 0.6 mg
  - Well-tolerated and favorable safety profile at all doses up to 180 mg SC weekly
- Stable 150 mg/mL SC dosage formulation<sup>3</sup>
- Potency and half-life expected to support up to Q4W dosing in hidradenitis suppurativa and potentially a longer dosing interval in other indications



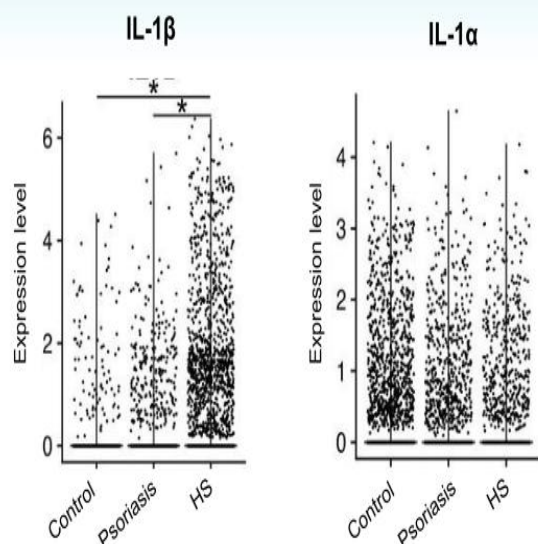


# AVTX-009 Potential Profile Advantages: IL-1 $\beta$ Specificity, Higher Affinity, Bioavailability, and Longer Half-Life than Lutikizumab



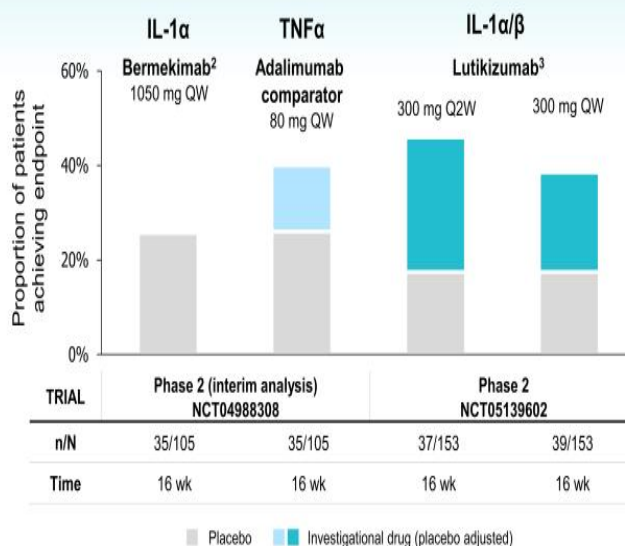
# Why Specificity Matters: IL-1 $\beta$ is the Predominant IL-1 Isoform that Drives Chronic Inflammation in HS

IL-1 Expression in HS Skin<sup>1,a</sup>



- IL-1 $\beta$  expression is elevated in HS skin vs no elevation of IL-1 $\alpha$ <sup>1</sup>
- Suggests that anti-IL-1 $\beta$  agents may be more effective than anti-IL-1 $\alpha$  in HS

Clinical Data for IL-1 Targeting Agents in HS (HiSCR75)



- Bimekimab, an IL-1 $\alpha$  specific mAb, performed no better than placebo in a Phase 2 study with adalimumab comparator arm<sup>1,2</sup>
- Lutikizumab, an IL-1 $\alpha/\beta$  targeting mAb, demonstrated favorable efficacy vs placebo in a phase 2 trial
- AVTX-009 IL-1 $\beta$  specificity may lead to class leading efficacy

# Why Affinity Matters in HS

Tissue distribution of mAbs is an active process that is impacted by tissue structure, osmotic pressure, and affinity for target antigens<sup>1</sup>

Restricted antibody penetration into the skin and pressurized lesions may require higher dosing in dermatologic conditions like HS<sup>2,3</sup>

## AVTX-009: High affinity and specificity

**Specifically targets IL-1 $\beta$ ,**  
enabling localized accumulation  
where expression is highest

**Superior affinity is expected to  
drive skin accumulation** in HS  
patients, aligning with IL-1 $\beta$ -rich  
environments<sup>1,4</sup>

**High tissue concentrations and  
strong binding** translate to  
potential for greater potency and  
improved efficacy

AVTX-009  
IL-1 $\beta$

avalo  
THERAPEUTICS

mAbs, monoclonal antibodies.

1. Ryman JT & Meibohm B. CPT Pharmacometrics Syst Pharmacol. 2017;6:576-588; 2. Humira. Package insert. AbbVie Inc.; 2024; 3. Cosentyx. Package insert. Novartis Pharmaceuticals Corporation; 2024; 4. Witte-Händel E, et al. J Invest Dermatol. 2019;139:1294-1305.

# Phase 2 LOTUS Trial in Hidradenitis Suppurativa (AVTX-009-HS-201, NCT06603077)

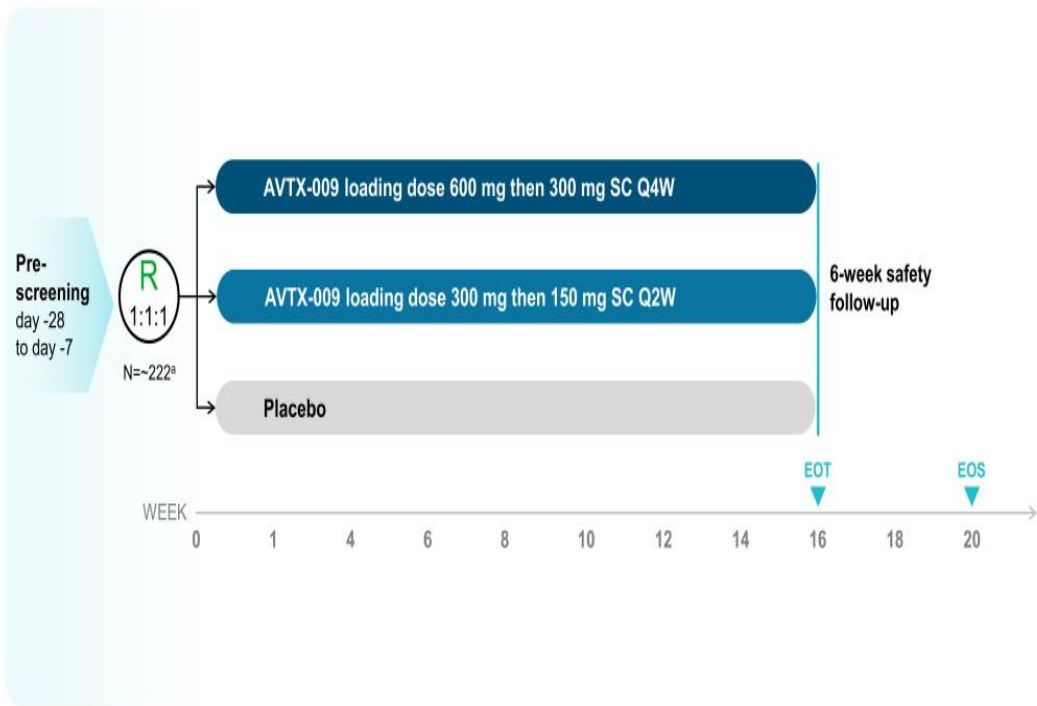
## Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

### Primary Study Endpoint

**Primary Endpoint:** Percentage of participants achieving HiSCR75 at 16 weeks

### Key Inclusion Criteria

- HS for ≥ 6 months prior to baseline
- Total AN count of ≥ 5 at baseline
- HS lesions must be present in ≥ 2 distinct anatomic areas
- At least one HS lesion that is Hurley stage II or III
- Enrollment of patients who are both biologic naïve and biologic experienced



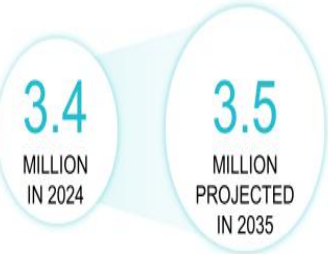
ADA, antidrug antibody; AN, abscess and inflammatory nodule; CRP, C-reactive protein; DLQI, dermatology life quality index; EOS, end of study; EOT, end of treatment; HiSCR, Hidradenitis Suppurativa Clinical Response; HiSQOL, hidradenitis suppurativa quality of life; HS, hidradenitis suppurativa; NRS30, numerical rating scale 30; PHQ-9, patient health questionnaire-9; PK, pharmacokinetics; Q2W, every 2 weeks; Q4W, every 4 weeks; R, randomize; SC, subcutaneous; TEAE, treatment emergent adverse event; TNF, tumor necrosis factor.

<sup>a</sup>Trial has 80% power to show a HiSCR75 response for each individual arm.



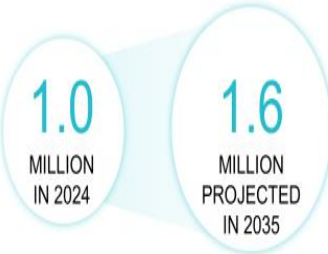
# Diagnosed and Treated HS Population is Projected to Grow Substantially into a \$10B+ Global Market by 2035<sup>1</sup>

## HS prevalence (U.S.)<sup>2</sup>



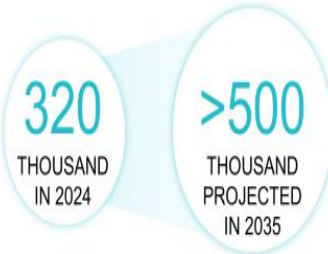
HS affects an estimated 1–4% of the population globally; 0.5% US population CAGR

## HS diagnosed and treated (U.S.)<sup>3</sup>



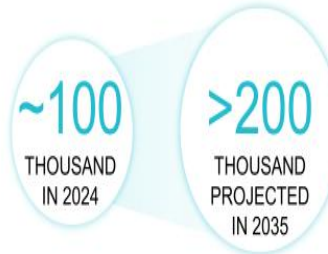
Growth in the number of diagnosed and treated patients from 30% to 45% of the total population, driven by new development and visibility with HCPs and patients

## Moderate-to-severe HS (U.S.)<sup>4</sup>



Increased recognition of disease leads to 60% growth of identified moderate to severe HS

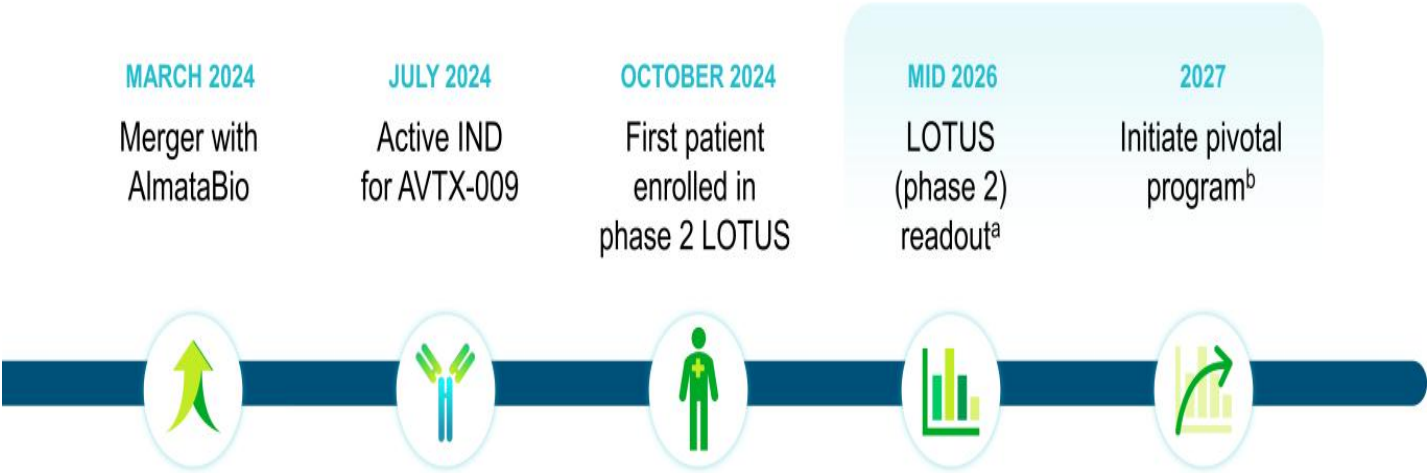
## Biologics treated (U.S.)<sup>5</sup>



New approvals will lead to more patients being treated with biologics, increasing to ~40% share of segment (evidenced by the recent quickly growing use of Cosentyx and Bimzelx)



# Timelines: Looking Forward



# Broad Potential for Indication Expansion:

## Clinical Rationale for IL-1 Targeting Therapies in Additional Disease States



### Arthritis Indications

- IL-1 targeting therapies approved in RA and acute gout flare<sup>1,2</sup>
- CANTOS study (Novartis): IL-1 $\beta$  blockage with canakinumab reduced total joint replacements in OA patients with high CRP<sup>3</sup>
- Mechanistic rationale extends to other crystal-induced arthritis (e.g., CPPD)



### Inflammatory Bowel Disease

- IL-1 $\beta$  is upregulated in inflammasome activation in Crohn's disease<sup>4</sup>
  - IL-1 activity may define a non-responder subset to current therapies<sup>5,6</sup>
  - Observed overlap of patients that have IBD and HS<sup>7,8</sup>
- Like in HS, current advanced therapies for IBD often fail to deliver adequate response



### Additional Indications with Established Clinical Proof of Concept

- While not a current focus for Avalo, IL-1 targeting therapies approved in rare autoinflammatory diseases (e.g., periodic fevers, DIRA, Still's disease and recurrent pericarditis)<sup>1,2,10</sup>
- CANTOS study (Novartis): canakinumab reduced major CV events in patients with prior MI and elevated CRP<sup>9</sup>
- Additional indications with supporting mechanistic and clinical rationales

# Avalo Summary (NASDAQ: AVTX)

## OUR APPROACH:

Next generation therapies targeting IL-1 $\beta$ , a master regulator of inflammation<sup>1</sup>

## LEAD ASSET AVTX-009:

A high-affinity, IL-1 $\beta$ -specific mAb<sup>2</sup>



**Differentiated Profile:** 15x higher affinity and longer half-life than lutikizumab; potential for best-in-class and best-in-disease profile with increased efficacy and less frequent dosing<sup>2-5</sup>

**Lead Indication – Hidradenitis Suppurativa (HS):** Projected to become a \$10B+ market by 2035<sup>5</sup> driven by growth in diagnosis and treatment + high patient need due to incomplete response rates for available anti-TNF and anti-IL-17 therapies

**Clinical Momentum:** Phase 2 LOTUS trial in HS is enrolling; topline data expected mid-2026

**Broad Potential:** Scientific and clinical rationale for expansion into additional IL-1 $\beta$ -driven diseases

**Strong Financial Foundation:** Cash runway into 2028

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NASDAQ: AVTX  
[www.avalotx.com](http://www.avalotx.com)





# Avalo Capitalization and Cash Position

As of March 31, 2025		Number of Shares
<b>Common stock</b>	Common shares outstanding <sup>1,2</sup>	10.8M
<b>Assuming conversion of preferred stock</b>	Preferred stock <sup>2</sup>	24.7M
<b>Adjusted share count</b>	<b>Adjusted common shares outstanding<sup>1,2</sup></b>	<b>35.5M</b>
<b>Adjusted market capitalization</b>	Stock price	\$8.01
	<b>Adjusted market capitalization</b>	<b>\$284.5M</b>



**Cash of approximately \$125 million as of March 31, 2025<sup>2</sup>,  
provides expected runway into 2028**

