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 2, 2025

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.)**

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

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 December 2, 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:

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.

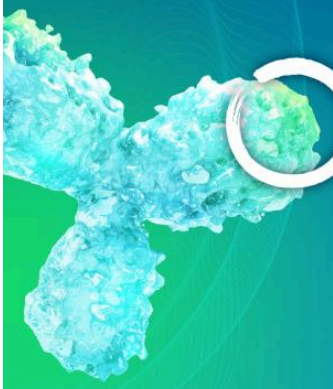
AVALO THERAPEUTICS, INC.

Date: December 2, 2025

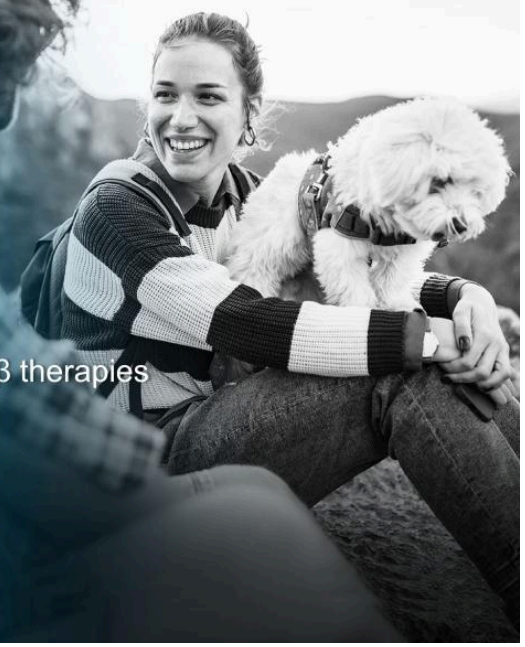
By: /s/ Christopher Sullivan
Christopher Sullivan
Chief Financial Officer

Exhibit 99.1

avalo THERAPEUTICS



One mission.



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

CORPORATE OVERVIEW

December 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. 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-1β Inhibition for Immune-Mediated Inflammatory Diseases

Lead compound AVTX-009 (anti-IL-1β 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-1α/β) demonstrated favorable phase 2 efficacy to market leaders and pipeline therapeutics in a refractory population that had failed anti-TNF therapy
- IL-1β (not IL-1α) is a key immunoregulator in HS, based on preclinical and clinical evidence[1,2,3]
- AVTX-009 has 15x higher affinity and a longer half-life than lutikizumab, potentially predictive of higher efficacy and less frequent dosing[4]

Phase 2 LOTUS trial in HS enrollment complete with topline data expected Q2 2026	HS market is expected to grow to > $10B by 2035[5]	AVTX-009 has the potential to treat additional immune-mediated inflammatory diseases	Expected cash runway into 2028

IL, interleukin; IND, investigational new drug application; mAB, monoclonal antibody; MOA, mechanism of action.

1. Vossen ARJV, et al. *J Invest Dermatol*. 2020;140(7):1463-1466.e2; 2. Kelly G, et al. *Br J Dermatol*. 2015;173(6):1431-1439; 3. Kimball AB, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA; 4. Bihorel S, et al. *AAPS J*. 2014;16(5):1009-1017; 5. HS Market Research 2024.

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

Chris Sullivan
Chief Financial Officer

Mittie Doyle, MD
Chief Medical Officer

Taylor Boyd
Chief Business Officer

Jennifer Riley
Chief Strategy Officer

Paul Varki
Chief Legal Officer

Colleen Matkowski
SVP, Global Regulatory Affairs, Quality Assurance

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

Ashley Ivanowicz
SVP, Human Resources

Kathleen Cohen
SVP, Clinical Development Operations

220+ Years
of experience in biotech/pharma

ARENA PHARMACEUTICALS · Johnson & Johnson · SUCAMPO The Science of Innovation · CSL Behring · AstraZeneca · AMARIN · BIOMARIN · ALEXION · idorsia · LONGBOARD PHARMACEUTICALS · Biogen · GSK · MARINUS · Takeda · flexion · Venatorx PHARMACEUTICALS · Shire · ABZENA · Aro BIOTHERAPEUTICS · OpGen · endo · braeburn · EY · OXB · Aralez PHARMACEUTICALS

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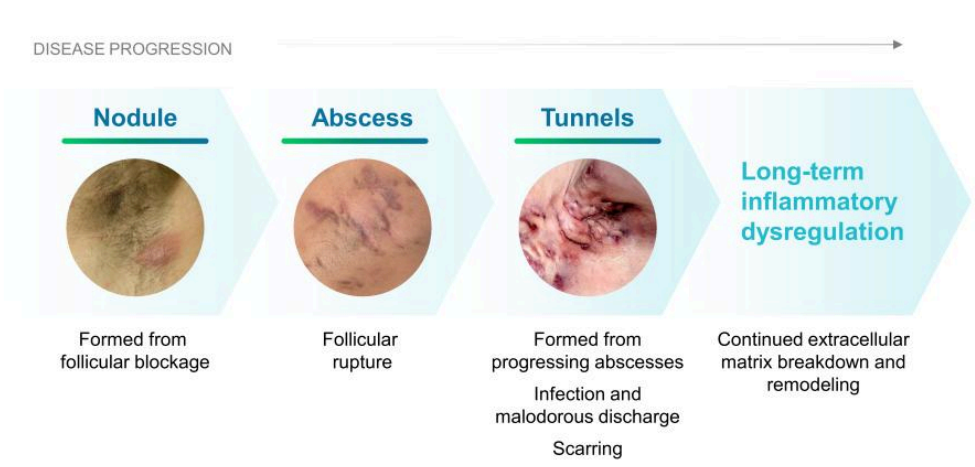
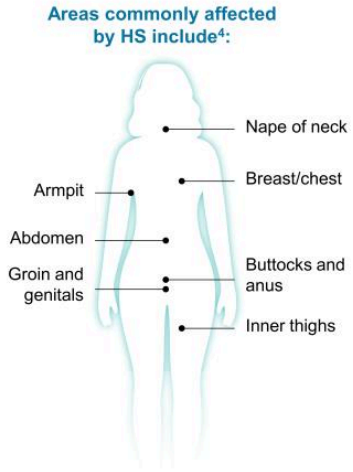
AVTX-009: Designed to Target the Inflammatory Driver of Hidradenitis Suppurativa (HS) to Address Significant Unmet Need

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



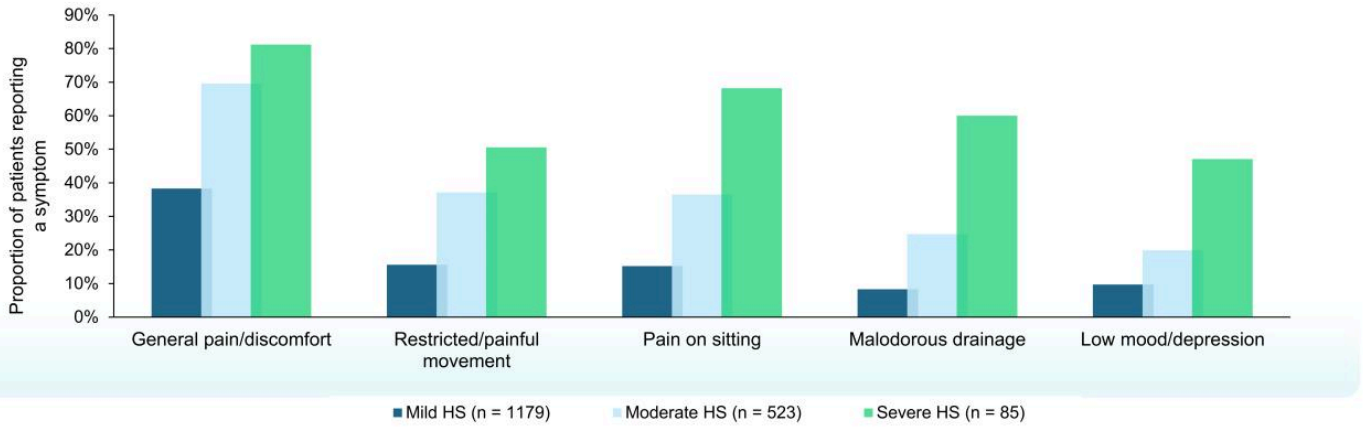


1. Diaz MJ, et al. *Curr Iss Mol Bio*. 2023;45:4400-4415; 2. Agnese ER, et al. *Cureus*. 2023;15(11):e49390; 3. de Oliveira ASLE, et al. *Biomolecules*. 2022;12(10):1371; 4. Ingram JR, et al. *J Eur Acad Dermatol Venereol*. 2022;36(9):1597-1605

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

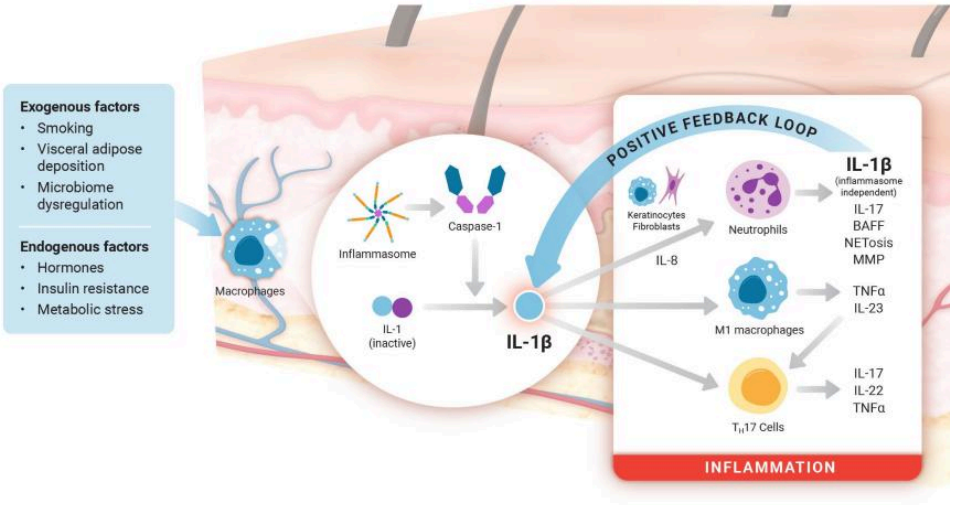
A large proportion of patients still report significant and life-disrupting symptoms with existing treatment options[1,2,a]



HS, hidradenitis suppurativa.
[a]Current treatments include antibiotics, retinoids, steroids, Cosentyx®, Humira®.
1. Ingram JR, et al. *J Eur Acad Dermatol Venereol*. 2022;36(9):1597-1605; 2. Kimball AB, et al. *Dermatol Ther (Heidelb)*. 2024;14(1):83-98.

IL-1β Plays a Central Role in the Pathophysiology of HS

- IL-1β is a key driver of the inflammatory cascade that leads to the destruction of the pilosebaceous unit
- IL-1β gene expression is up to 100x increased in HS lesions compared to skin in healthy controls[1,2]
- IL-1β is upstream of IL-17 and TNFα, both major effectors of inflammation[3]
- Clinical benefit in HS has been observed with anti-IL-1 drugs[4]

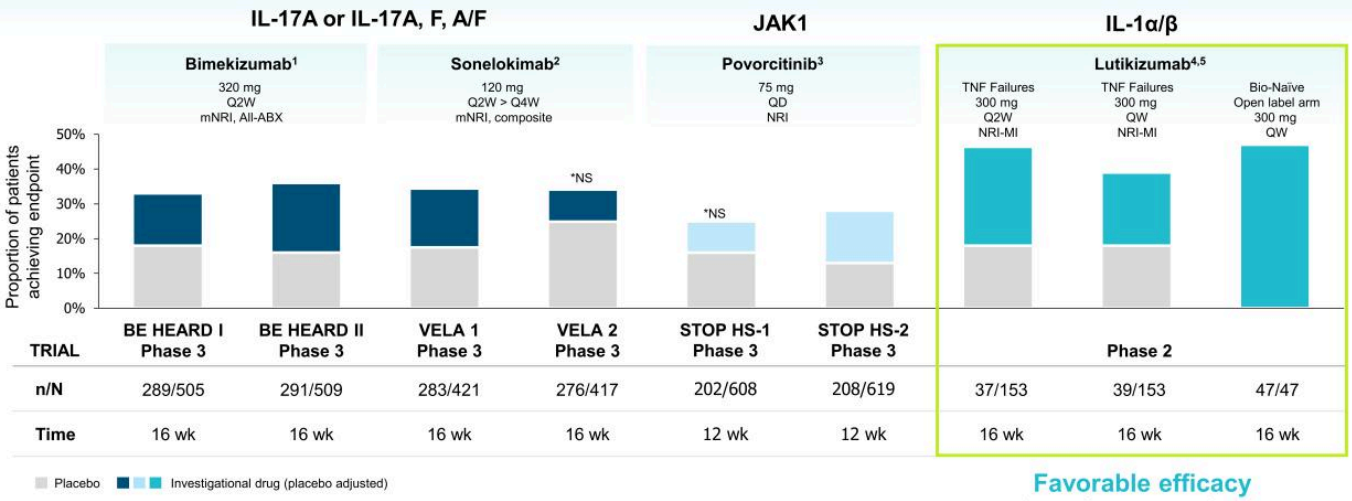


DAMP, damage-associated molecular pattern molecule; DC, dendritic cell; HS, hidradenitis suppurativa; IL, interleukin; R, receptor; PAMP, pathogen-associated molecular pattern molecule.
Figure adapted from Agnese ER et al. Cureus. 15(11):e49390. Creative Commons license, CC-BY 4.0.

1. Vossen ARJV, et al. *J Invest Dermatol*. 2020;140(7):1463-1466.e2; 2. Kelly G, et al. *Br J Dermatol*. 2015;173(6):1431-1439; 3. Agnese ER et al. *Cureus*. 15(11):e49390; 4. Kimball AB, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

Phase 2 Lutikizumab Data Highlights the Role for IL-1 in HS

HiSCR75



Favorable efficacy
in a refractory population (71% Hurley stage III) that had already failed anti-TNF therapy and strong open label data in bio-naïve population

*NS, not statistically significant ; All-ABX, patients who received any systemic antibiotic (new or increased dose) or who discontinued due to an adverse event or absence of efficacy were treated as nonresponders at all subsequent visits; HiSCR, hidradenitis suppurativa clinical response; IL, interleukin; JAK1, janus kinase 1; mNRI, modified non-responder imputation; MI, multiple imputation, NRI, non-responder imputation; TNF, tumor necrosis factor; wk, week; QD, daily; QW, weekly, Q2W, every other week; Q4W, ever 4 weeks.

1. Kimball AB, et al. *Lancet*. 2024;403(10443):2504-2519; 2. Moonlake data presentation, September 29, 2025; 3.Incyte data presentation March 17, 2025 4. Kimball AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA; 5. Kimball AB, Lima et al. Presented at European Academy of Dermatology and Venerology 2025; September 17-20, 2025; Paris, France.

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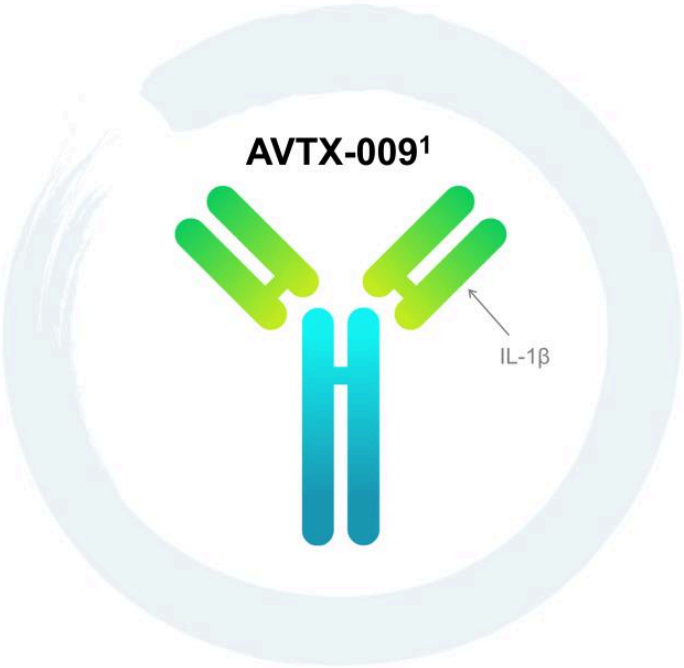
AVTX-009 Is A Highly Potent, Specific Inhibitor of IL-1β

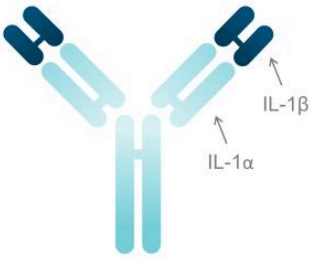
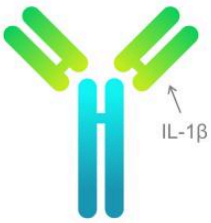
- Clinical experience
  - 245 patients studied in phase 1 and phase 2 trials[2,3-6]
  - Significant and rapid lowering of inflammatory biomarkers after a single dose of 0.6 mg
  - Well-tolerated and favorable safety profile at all doses up to 180 mg SC weekly
- Stable 150 mg/mL SC dosage formulation[3]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



IL, interleukin; IV, intravenous; KD, dissociation constant; Q4W, every 4 weeks; SC, subcutaneous.

1. Bihorel S, et al. *AAPS J.* 2014;16(5):1009-1017; 2. Sloan-Lancaster J, et al. *Diabetes Care.* 2013;36(8):2239-2246; 3. Data on file;
4. NCT04983732. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04983732; 5. NCT00942188. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT00942188; 6. NCT00380744. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT00380744.

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

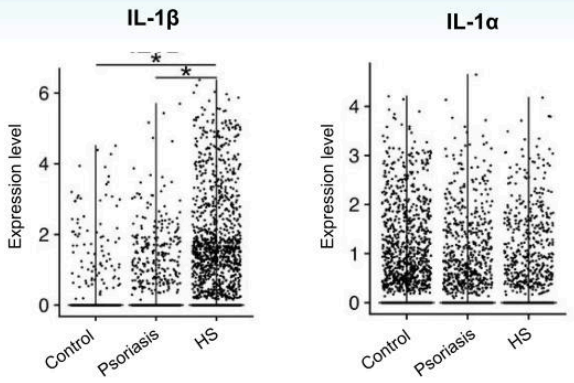
	Lutikizumab[1,2]	AVTX-009[3]		Potential AVTX-009 profile advantages in HS
				
Specificity	IL-1 (α&β)	**IL-1β**	✓	Potential to translate to higher efficacy
IL-1β binding affinity	44 K_D (pM)	**<3 K_D (pM)**	✓	
Subcutaneous bioavailability	46%	**73%**	✓	
Half-life	10-14 days	**19 days**	✓	Potential for less frequent dosing
Dosing evaluated in HS study	Q1W & Q2W[4]	**Q2W & Q4W[5]**	✓	

KD, dissociation constant; pM, picomolar.

1. Lacy SE, et al. *mAbs*. 2015;7(3):605-619; 2. Wang SX, et al. *Osteoarthritis Cartilage*. 2017;25(12):1952-1961; 3. Bihorel S, et al. *AAPS J*. 2014;16(5):1009-1017; 4. Clinicaltrials.gov. NCT06468228. https://clinicaltrials.gov/study/NCT06468228. Accessed November 26, 2024; 5. Clinicaltrials.gov. NCT06603077. https://clinicaltrials.gov/study/NCT06603077. Accessed November 26, 2024.

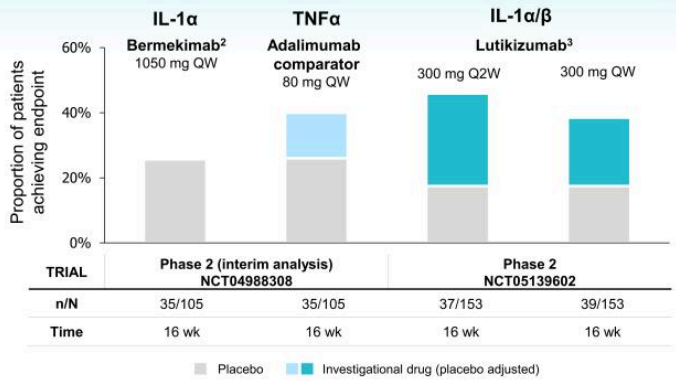
Why Specificity Matters: IL-1β is the Predominant IL-1 Isoform that Drives Chronic Inflammation in HS

IL-1 Expression in HS Skin[1,a]



- IL-1β expression is elevated in HS skin vs no elevation of IL-1α[1]
- Suggests that anti-IL-1β agents may be more effective than anti-IL-1α in HS

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



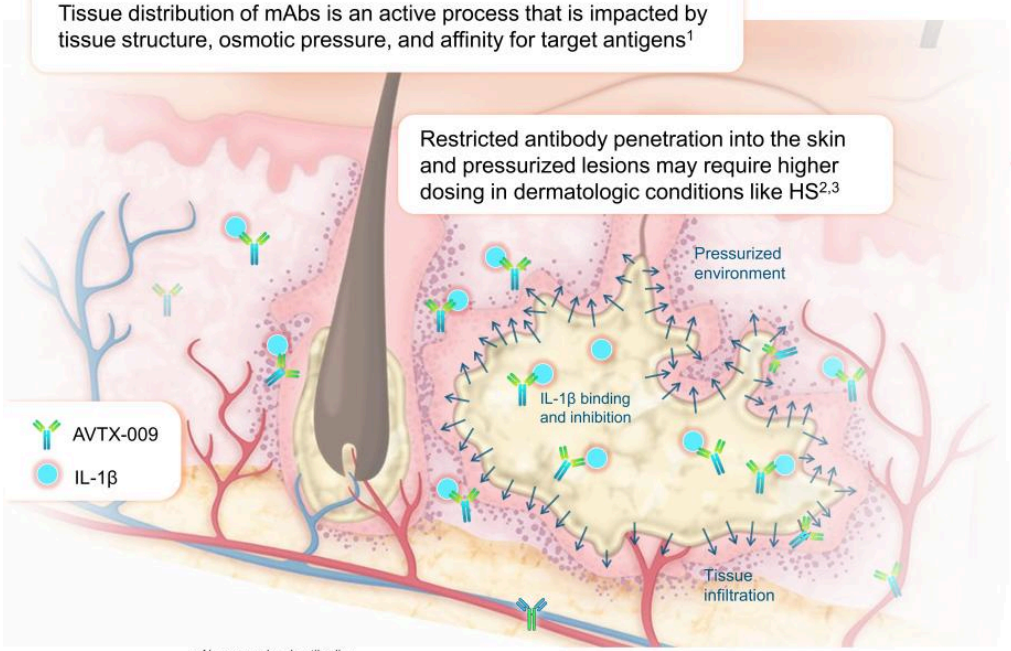
TRIAL	Phase 2 (interim analysis) NCT04988308		Phase 2 NCT05139602	
n/N	35/105	35/105	37/153	39/153
Time	16 wk	16 wk	16 wk	16 wk

- Bermekimab, an IL-1α specific mAb, performed no better than placebo in a Phase 2 study with adalimumab comparator arm[1,2]
- Lutikizumab, an IL-1α/β targeting mAb, demonstrated favorable efficacy vs placebo in a phase 2 trial
- AVTX-009 IL-1β specificity may lead to class leading efficacy

HiSCR, hidradenitis suppurativa clinical response; HS, hidradenitis suppurativa; IL, interleukin; mAb, monoclonal antibody; QW, weekly, Q2W, every other week; wk, week.
[a]Figure adapted from Kim JK et al. Creative commons license. CC-BY 4.0.
1. Kim JK, et al. *JACI* 2023;152:656-666; 2. ClinicalTrials.gov identifier: NCT04988308. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04988308; 3. Kimball AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

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[1]



AVTX-009:
High affinity and specificity

Specifically targets IL-1β, enabling localized accumulation where expression is highest

High affinity is expected to drive skin accumulation in HS patients, aligning with IL-1β-rich environments[1,4]

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

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)

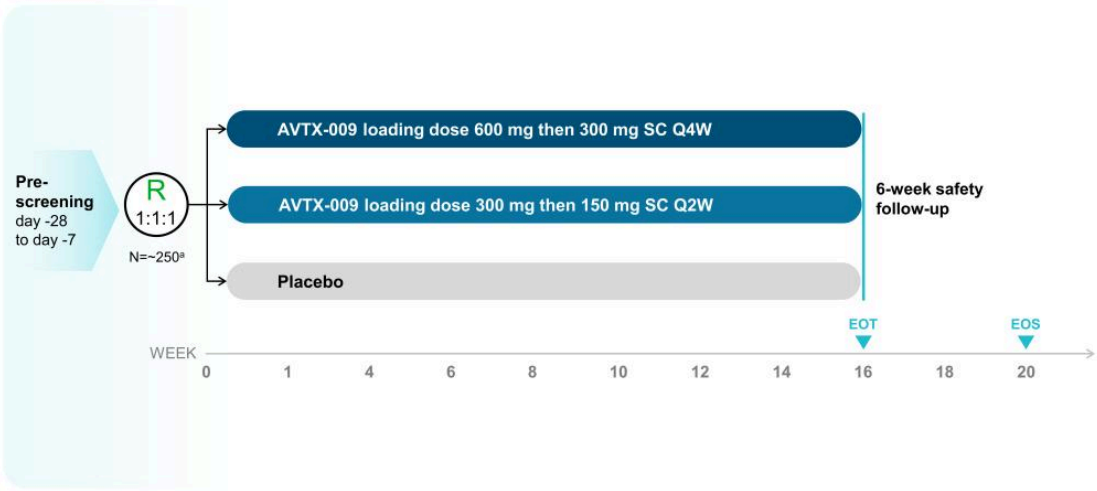
Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

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

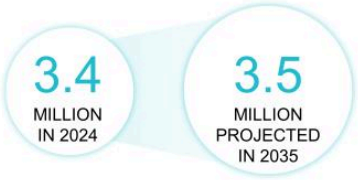


ADA, antidrug antibody; AN, abscess and inflammatory nodule; CRP, C-reactive protein; DLQI, dermatology life quality index; EOS, end of study; EOT, end of treatment; HiSCR, Hidradenitis Suppurativa Clinical Response; HiSQOL, hidradenitis suppurativa quality of life; HS, hidradenitis suppurativa; NRS30, 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.

[a]Trial has 80% power to show a HiSCR75 response for each individual arm.

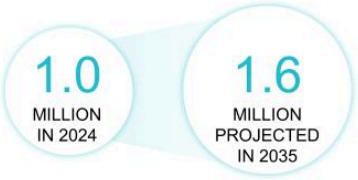
Diagnosed and Treated HS Population is Projected to Grow Substantially into a $10B+ Global Market by 2035[1]

HS prevalence (U.S.)[2]



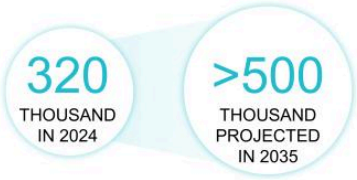
HS affects an estimated 1–4% of the population globally; 0.5% US population CAGR

HS diagnosed and treated (U.S)[3]



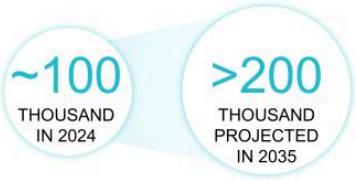
Growth in the number of diagnosed and treated patients from 30% to 45% of the total population, driven by new development and visibility with HCPs and patients

Moderate-to-severe HS (U.S.)[4]



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

Biologics treated (U.S.)[5]



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)

HCP, healthcare provider; HS, hidradenitis suppurativa; U.S., United States.

1. HS Market Research 2024. Avalo Therapeutics Data on File; 2. Nguyen TV, et al. J Eur Acad Dermatol Venereol. 2021;35(1):50-61; 3. Garg AX, et al. *Dermatol Ther.* 2022;3:581-594; 4. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605; 5. Rinderknecht FB, Naik HB. *Int J Womens Dermatol.* 2024;10(1):e130.

Timelines: Looking Forward

MARCH 2024	JULY 2024	OCTOBER 2024	OCTOBER 2025	Q2 2026	2027
Merger with AlmataBio	Active IND for AVTX-009	First patient enrolled in phase 2 LOTUS study	Enrollment completed in phase 2 LOTUS study	LOTUS (phase 2) readout[a]	Initiate pivotal program[b]

IND, investigational new drug application.
[a]Projected; [b]Pending readout from phase 2.

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[1,2]
- CANTOS study (Novartis): IL-1β blockage with canakinumab reduced total joint replacements in OA patients with high CRP[3]
- Mechanistic rationale extends to other crystal-induced arthritis (e.g., CPPD)

Inflammatory Bowel Disease

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

Avalo is currently assessing additional immunology indications for investment

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)[1,2,10]
- CANTOS study (Novartis): canakinumab reduced major CV events in patients with prior MI and elevated CRP[9]
- Additional indications with supporting mechanistic and clinical rationales

CRP, C-reactive protein; CV, cardiovascular; DIRA, deficiency of interleukin receptor 1 antagonist; HS, hidradenitis suppurativa; IBD, inflammatory bowel disease; MI, myocardial infarction; OA, osteoarthritis; RA, rheumatoid arthritis.

1. Ilaris. Package insert. Novartis Pharmaceuticals Corporation; 2023; 2. Kineret. Package insert. Swedish Orphan Biovitrum AB; 3. Schieker, et al. Annals of Internal Medicine. 2020;173(7):509-515; 4. Mao L, et al. Front Immunol. 2018;9:2566; 5. Friedrich M, et al. Nat Med. 2021;27(11):1970-1981; 6. Cader MZ, Kaser A. Nat Med. 2021;27(11):1870-1871; 7. Chen WT, Chi CC. JAMA Dermatol. 2019;155(9):1022-1027; 8. Zhang M, et al. World J Clin Cases. 2021;9(15):3506-3516; 9. Ridker, et al. NEJM . 2017;377(12):1119-1131; 10. Arcalyst. Package insert. Kiniksa Pharmaceuticals (UK), Ltd.; 2021.

Avalo Summary (NASDAQ: AVTX)

OUR APPROACH:
Next generation therapies targeting IL-1β, a master regulator of inflammation[1]

LEAD ASSET AVTX-009:
A high-affinity, IL-1β–specific mAb[2]

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

Lead Indication – Hidradenitis Suppurativa (HS): Projected to become a $10B+ market by 2035[5] 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 enrollment complete; topline data expected Q2 2026

Broad Potential: Scientific and clinical rationale for expansion into additional IL-1β–driven diseases

Strong Financial Foundation: Expected cash runway into 2028

IL, interleukin; mAB, monoclonal antibody.
1.Dinarello CA. Immunol Rev. 2018;281(1):8-27; 2. Bihorel S, et al. AAPS J. 2014;16(5):1009-1017; 3. Lacy SE, et al. mAbs. 2015;7(3):605-619; 2. Wang SX, et al. Osteoarthritis Cartilage. 2017;25(12):1952-1961; 4. Clinicaltrials.gov. NCT06468228. https://clinicaltrials.gov/study/NCT06468228. Accessed November 26, 2024; 5. Clinicaltrials.gov. NCT06603077. https://clinicaltrials.gov/study/NCT06603077. Accessed November 26, 2024.; 5. HS Market Research 2024.

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Appendix

Key Financial Metrics

As of September 30, 2025		Number of Shares
Common stock	Common shares outstanding[1,2]	17.8M
Assuming conversion of preferred stock	Preferred stock[2]	19.4M
Adjusted share count	**Adjusted common shares outstanding[1,2]**	**37.2M**
Adjusted market capitalization	Stock price	$12.71
	Adjusted market capitalization	**$472.7M**

Cash, cash equivalents and short-term investments of approximately $112 million as of September 30, 2025[2], provides expected runway into 2028

1. Does not include 5.3M of stock options, restricted stock units and performance stock units outstanding resulting in a fully dilutive share count of 42.5M as of September 30, 2025, 2. Cash, cash equivalents and short-term investments, common shares outstanding, and preferred shares outstanding as of September 30, 2025 are preliminary, unaudited and subject to change