
**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): January 12, 2026

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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 2.02 Results of Operations and Financial Condition.

On January 12, 2026, Avalo Therapeutics, Inc. (the “Company”) disclosed in an updated investor presentation posted on its website that the Company estimates it had approximately \$98 million of cash, cash equivalents and short-term investments as of December 31, 2025.

The information contained in Item 2.02 of this Current Report on Form 8-K is unaudited and preliminary and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2025 and its results of operations for the year ended December 31, 2025. The Company’s actual results for the year ended December 31, 2025 will be included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025 and may differ materially from the above estimate.

The information contained in Item 2.02 of this Current Report on Form 8-K is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

The Company has 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 to this Current Report on Form 8-K and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Investor Presentation</u>
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: January 12, 2026

By: /s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer

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One mission.

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

CORPORATE OVERVIEW

January 2026 | 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-1 β Inhibition for Immune-Mediated Inflammatory Diseases



Lead compound AVTX-009 (anti-IL-1 β 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 α/β) demonstrated favorable phase 2 efficacy to market leaders and pipeline therapeutics in a refractory population that had failed anti-TNF therapy
- IL-1 β (not IL-1 α) is a key immunoregulator in HS, based on preclinical and clinical evidence^{1,2,3}
- AVTX-009 has higher affinity and a longer half-life than lutikizumab, potentially predictive of higher efficacy and less frequent dosing⁴

Phase 2 LOTUS trial
in HS enrollment
complete with topline
data expected Q2 2026

HS market is
expected to grow to
> \$10B by 2035⁵

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



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

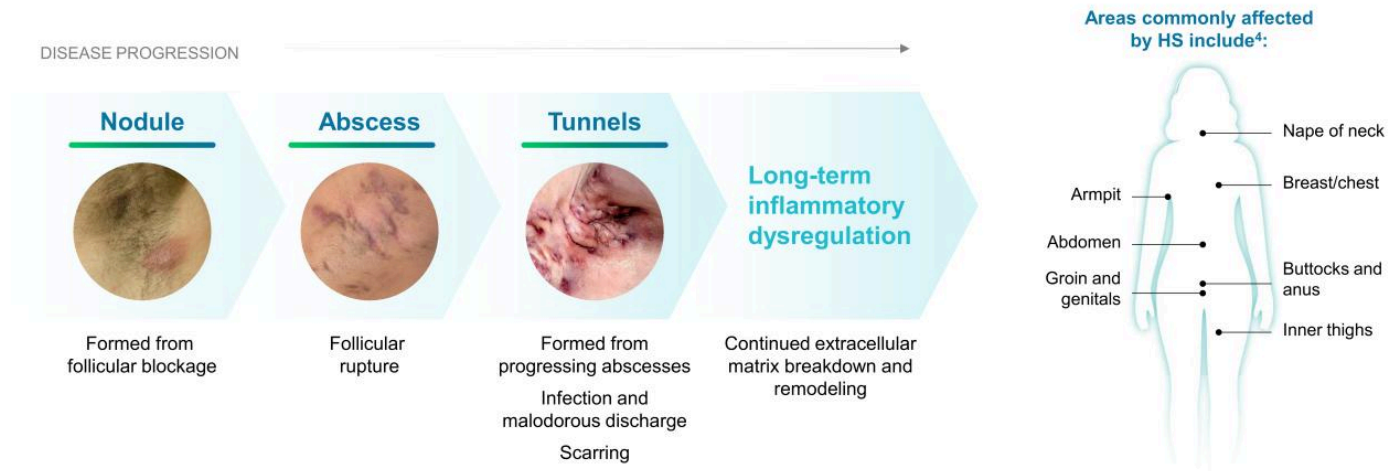




AVTX-009: Designed to Target the
Inflammatory Driver of Hidradenitis
Suppurativa (HS) to Address
Significant Unmet Need

Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction

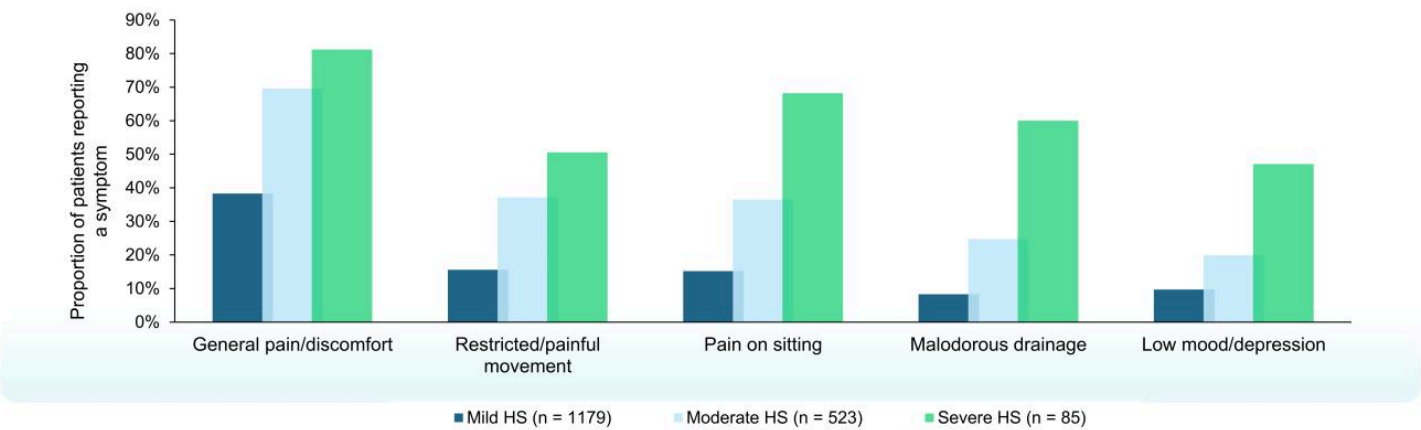
HS is a chronic, often debilitating inflammatory skin disease that causes painful nodules, abscesses, and tunnels to form under the skin



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

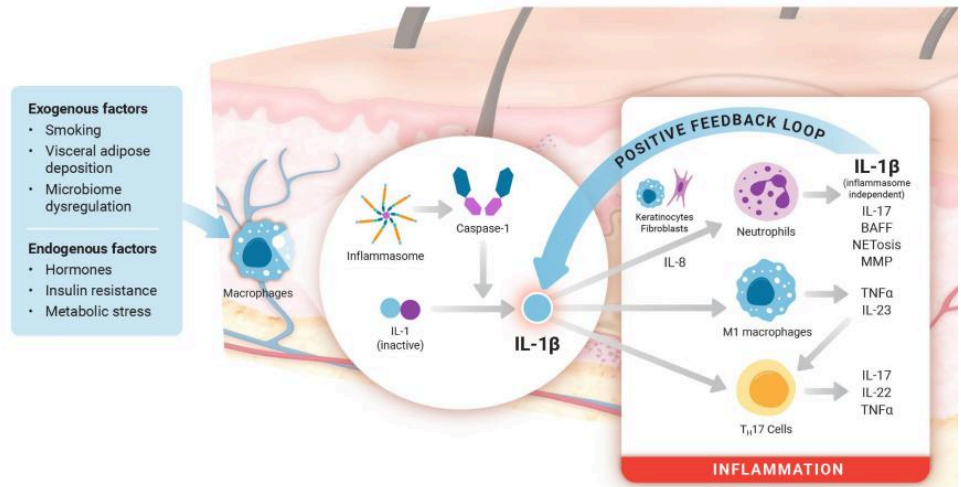
Severe Impact on Quality of Life

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



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

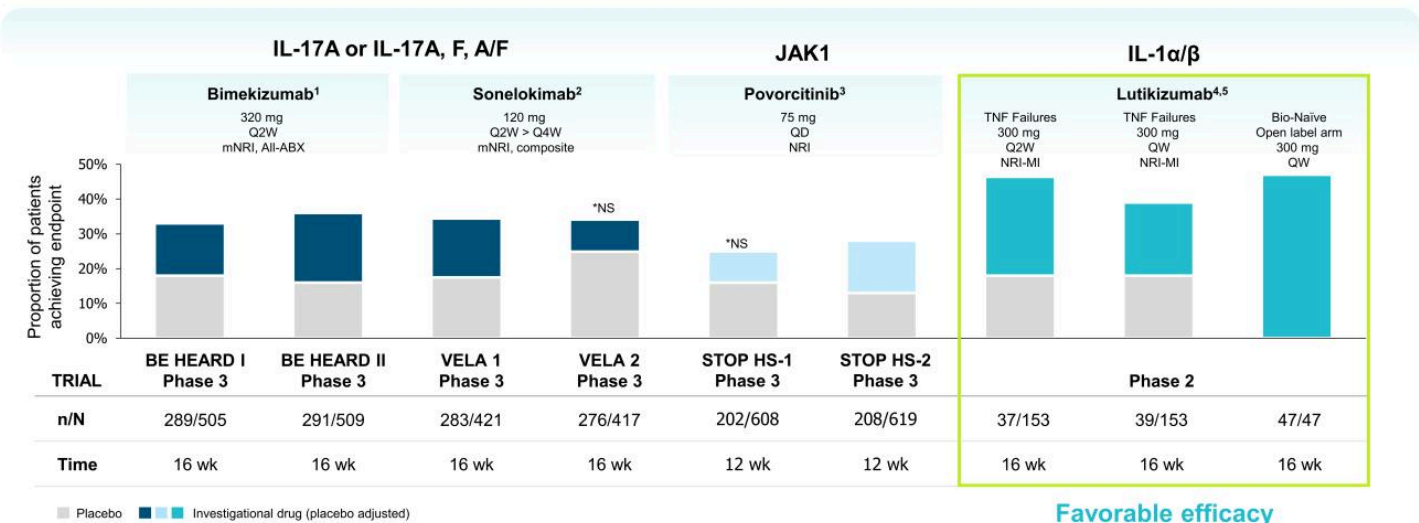
- IL-1 β is a key driver of the inflammatory cascade that leads to the destruction of the pilosebaceous unit
- IL-1 β gene expression is up to 100x increased in HS lesions compared to skin in healthy controls^{1,2}
- IL-1 β is upstream of IL-17 and TNF α , both major effectors of inflammation³
- Clinical benefit in HS has been observed with anti-IL-1 drugs⁴



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



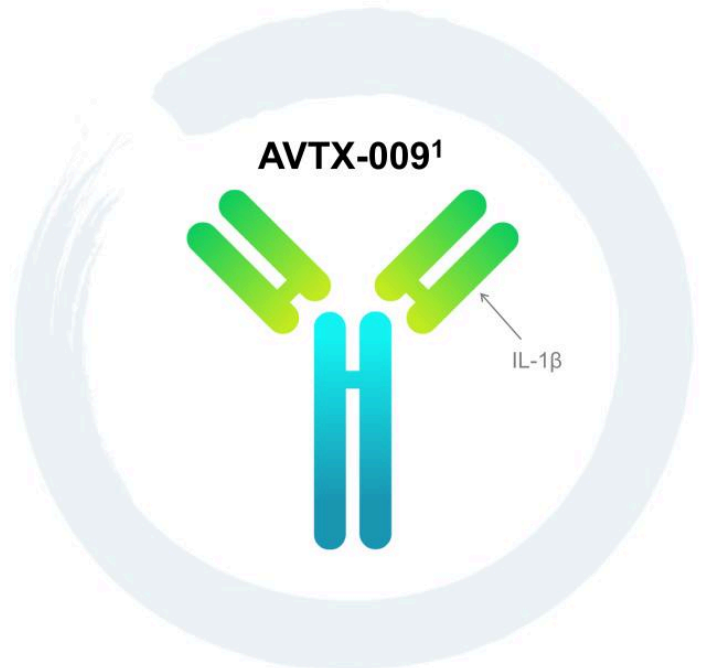
*NS, not statistically significant ; All-ABX, patients who received any systemic antibiotic (new or increased dose) or who discontinued due to an adverse event or absence of efficacy were treated as nonresponders at all subsequent visits; HiSCR, hidradenitis suppurativa clinical response; IL, interleukin; 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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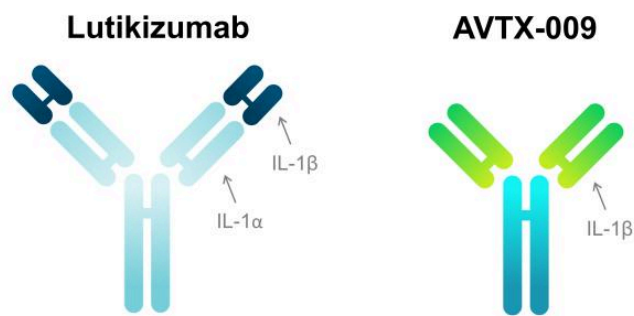
Favorable efficacy
in a refractory population
(71% Hurley stage III) that had already
failed anti-TNF therapy and strong
open label data in bio-naïve population

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

- 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 formulation³
- 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 β Specificity, High Affinity, Bioavailability, and Long Half-Life



Specificity	IL-1 (α & β)	IL-1 β	✓
IL-1 β binding affinity	21 K _D (pM) ¹	<3 K _D (pM) ³	✓
Subcutaneous bioavailability	46% ²	73% ⁴	✓
Half-life	10-14 days ²	19 days ⁴	✓
Dosing evaluated in HS study	Q1W & Q2W ⁵	Q2W & Q4W ⁶	✓

Potential AVTX-009 profile advantages in HS

Potential to translate to higher efficacy

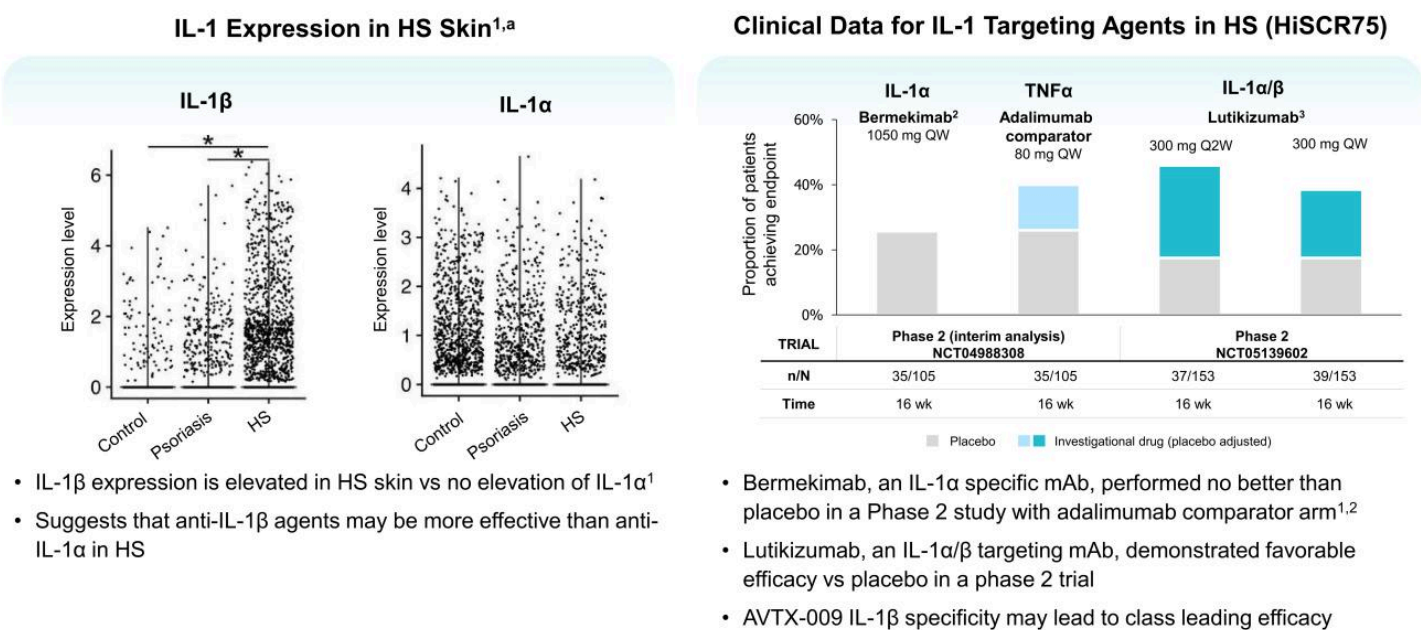
Potential for less frequent dosing

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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. Data on file, Clinicaltrials.gov. NCT06468228. <https://clinicaltrials.gov/study/NCT06468228>. Accessed November 26, 2024; 5. Clinicaltrials.gov. NCT06468228. <https://clinicaltrials.gov/study/NCT06468228>. Accessed November 26, 2024; 6. Clinicaltrials.gov. NCT06603077. <https://clinicaltrials.gov/study/NCT06603077>. Accessed November 26, 2024.

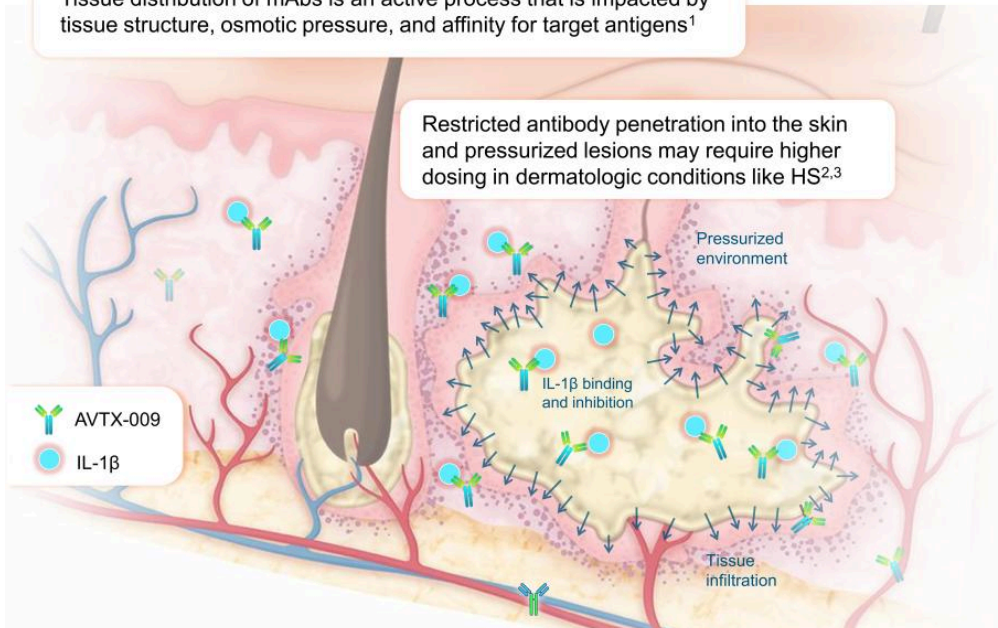
Why Specificity Matters: IL-1β is the Predominant IL-1 Isoform that Drives Chronic Inflammation in HS



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 antigens¹

Restricted antibody penetration into the skin and pressurized lesions may require higher dosing in dermatologic conditions like HS^{2,3}



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

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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)

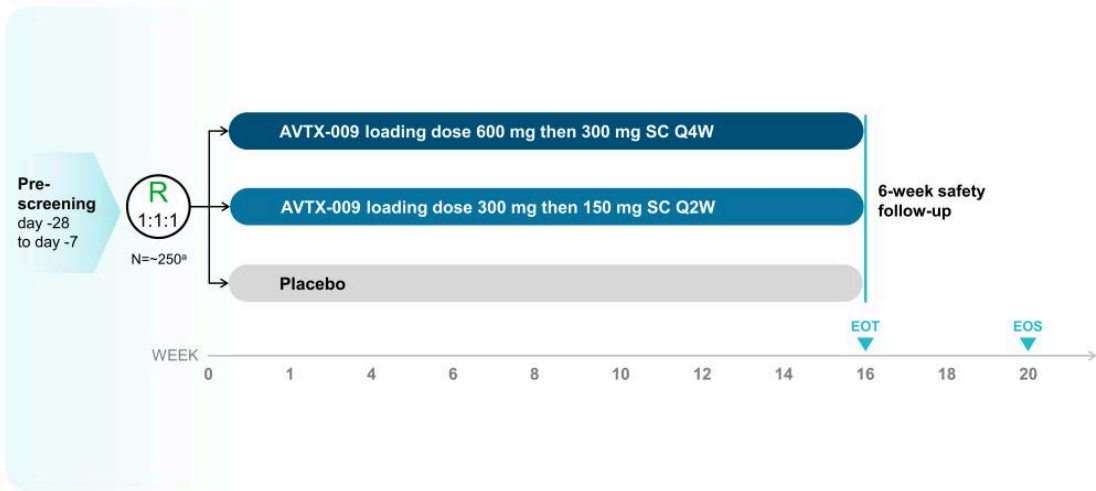
Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

Primary Study Endpoint

Primary Endpoint: Percentage of participants achieving HiSCR75 at 16 weeks

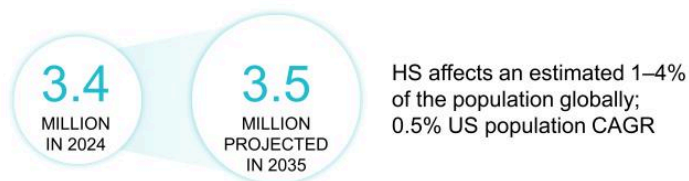
Key Inclusion Criteria

- 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

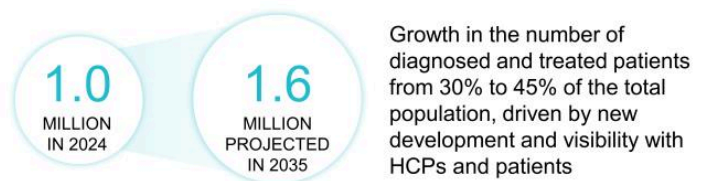


Diagnosed and Treated HS Population is Projected to Grow Substantially into a \$10B+ Global Market by 2035¹

HS prevalence (U.S.)²



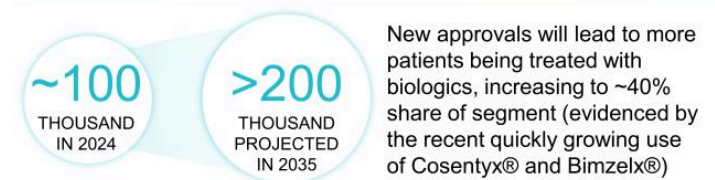
HS diagnosed and treated (U.S.)³



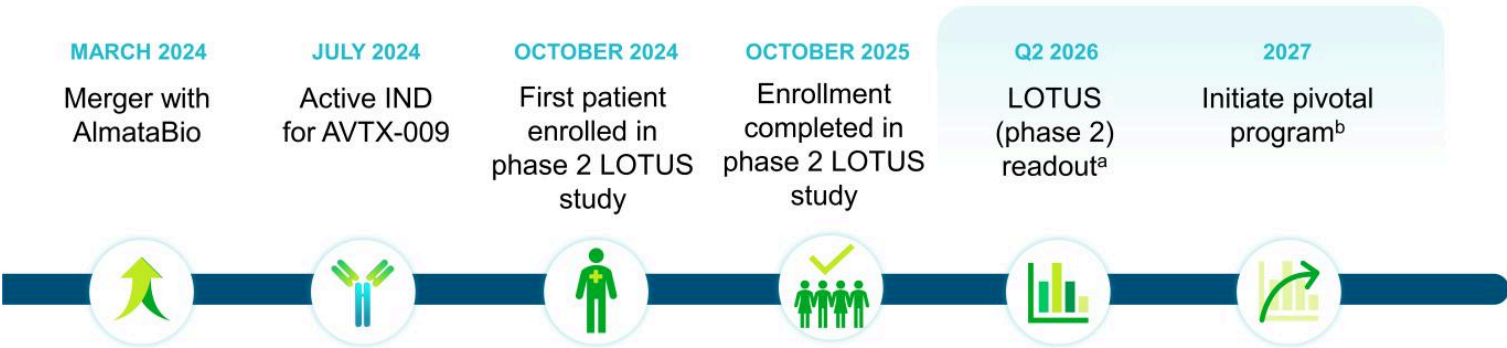
Moderate-to-severe HS (U.S.)⁴



Biologics treated (U.S.)⁵



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^{1,2}
- CANTOS study (Novartis): IL-1 β blockage with canakinumab reduced total joint replacements in OA patients with high CRP³
- Mechanistic rationale extends to other crystal-induced arthropathies (e.g., CPPD)



Inflammatory Bowel Disease

- IL-1 β is upregulated in inflammasome activation in Crohn's disease⁴
 - 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



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 CRP⁹
- Additional indications with supporting mechanistic and clinical rationales

Avalo Summary (NASDAQ: AVTX)

OUR APPROACH:

Next generation therapies targeting IL-1 β , a master regulator of inflammation¹

LEAD ASSET AVTX-009:

A high-affinity, IL-1 β -specific mAb²



Differentiated Profile: 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 dosing²⁻⁵

Lead Indication – Hidradenitis Suppurativa (HS): Projected to become a \$10B+ market by 2035⁵ 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-1 β -driven diseases

Strong Financial Foundation: Expected cash runway into 2028

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NASDAQ: AVTX
www.avalotx.com



Key Financial Metrics

As of December 31, 2025		Number of Shares
Common stock	Common shares outstanding ²	18.5M
Assuming conversion of preferred stock	Preferred stock ²	18.8M
Adjusted share count	Adjusted common shares outstanding ^{1,2}	37.3M
Adjusted market capitalization	Stock price	\$18.16
	Adjusted market capitalization	\$677.5M



Cash, cash equivalents and short-term investments of approximately \$98M as of December 31, 2025², provides expected runway into 2028

