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 5, 2024

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 December 5, 2024, Avalo Therapeutics, Inc. (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. 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 5, 2024

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

Exhibit 99.1

Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

December 2024

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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 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: Developing Targeted Therapies for Immune Dysregulation

- Lead compound: AVTX-009 (anti-IL-1β mAb) has the potential for "best-in-disease" profile in hidradenitis suppurativa (HS)
  - Favorable POC validation in HS:
    - Abbvie's lutikizumab (IL-1α/β) demonstrated comparable efficacy to market leaders and pipeline therapeutics, and in a refractory population that had failed anti-TNF therapy
  - IL-1β (not IL-1α) is a dominant immunoregulator in HS, based on pre-clinical and clinical evidence
  - AVTX-009 has 15x higher affinity and a longer half-life than lutikizumab, potentially predictive of higher efficacy and more convenient dosing

Phase 2 LOTUS trial initiated with Topline data expected in 2026

HS is expected to grow to > $10B by 2035[1]

AVTX-009 has the potential to treat multiple immune-mediated diseases

Expected cash runway into at least 2027

IL, interleukin; IND, investigational new drug application; mAB, monoclonal antibody; MOA, mechanism of action.
1. HS Market Research 2024.

Avalo Management Team
175+ Years of Experience in Biotech/Pharma

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

Garry A. Neil, MD
Chief Executive Officer
Chairman of the Board

Mittie Doyle, MD
Chief Medical Officer

Chris Sullivan
Chief Financial Officer

Paul Varki
Chief Legal Officer

Colleen Matkowski
SVP, Global Regulatory Affairs,
Quality Assurance

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

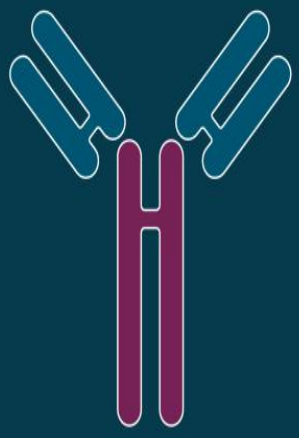
Lisa Hegg, PhD
SVP, Program Management, Corporate
Infrastructure, Clinical Operations

AVTX-009

A Highly Potent, Specific Inhibitor of IL-1β

- Originally developed by Eli Lilly[1,2]
- Stable 150 mg/mL dosage formulation[3]
  - SC and IV administration
  - Initial presentation: prefilled syringe
    Post-approval plan: autoinjector
- 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
- Potency and half-life expected to support Q4W dosing

AVTX-009[1]



<3 IL-1β KD (pM) Binding Affinity for IL-1β

73% Subcutaneous Bioavailability

19-day Half-Life

IL, interleukin; IV, intravenous; K_D, 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.

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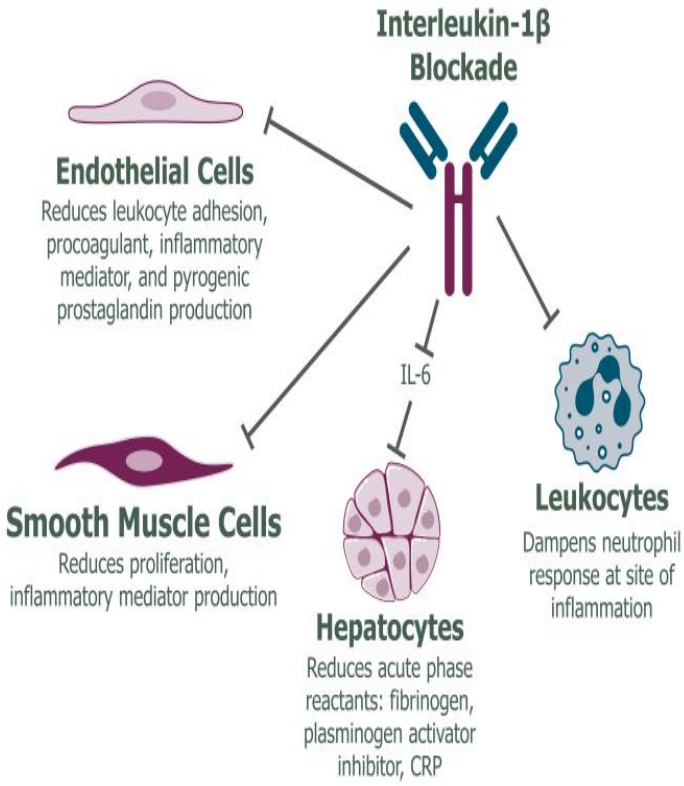
IL-1β is a Master Regulator of Inflammation

- IL-1β is a central driver of the inflammatory process[1] and activates immune cells that generate proinflammatory cytokines including IL-6, TNF-α, and IL-17
- Clinically validated and de-risked MOA
  - Inhibition of IL-1β has been shown to be effective and safe in a variety of autoimmune and inflammatory diseases, including hidradenitis suppurativa[1-3]
  - Well-established class safety and tolerability with 3 approved products, >12,000 patients studied in clinical trials, and 13+ years real world experience[4-7]



CRP, C-reactive protein; IL, interleukin; TNF, tumor necrosis factor.

1. Dinarello CA. *Immunol Rev.* 2018;281(1):8-27; 2. Kany S, et al. *Int J Mol Sci.* 2019;20(23):6008; 3. Kimball AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA; 4. Ridker PM, et al. *NEJM.* 2017;377(12):119-1131; 5. Ilaris®. Package insert. Novartis Pharmaceuticals Corporation; 2023; 6. Kineret®. Package insert. Swedish Orphan Biovitrum AB; 2000; 7. Arcalyst®. Package insert. Kiniksa Pharmaceuticals (UK), Ltd.; 2021.

AVTX-009 Opportunity in Hidradenitis Suppurativa (HS)

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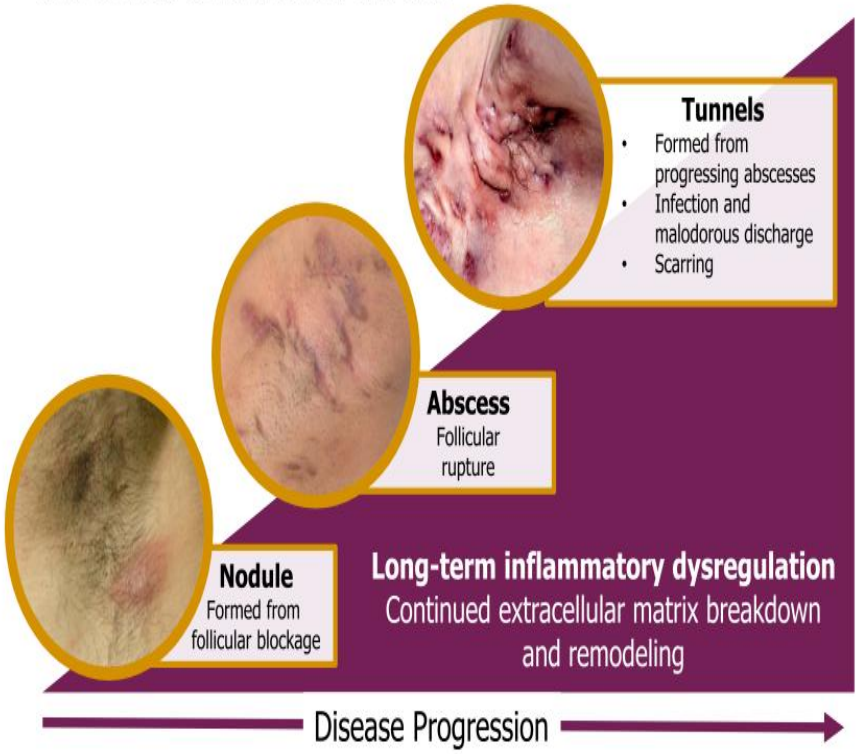
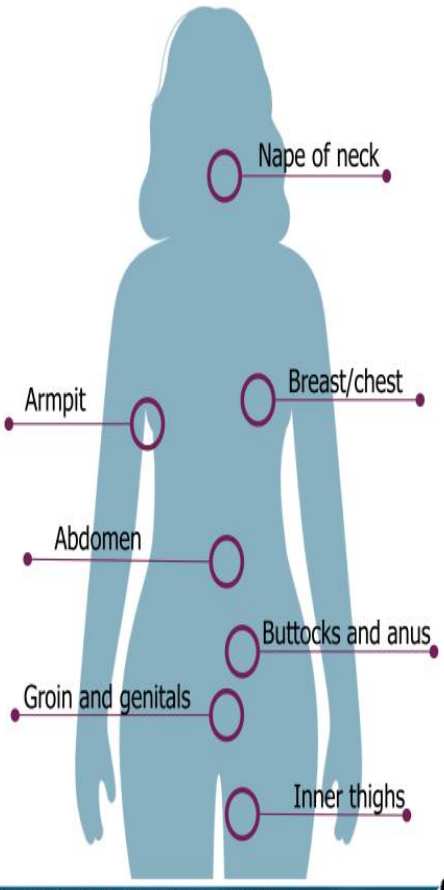
Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction

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



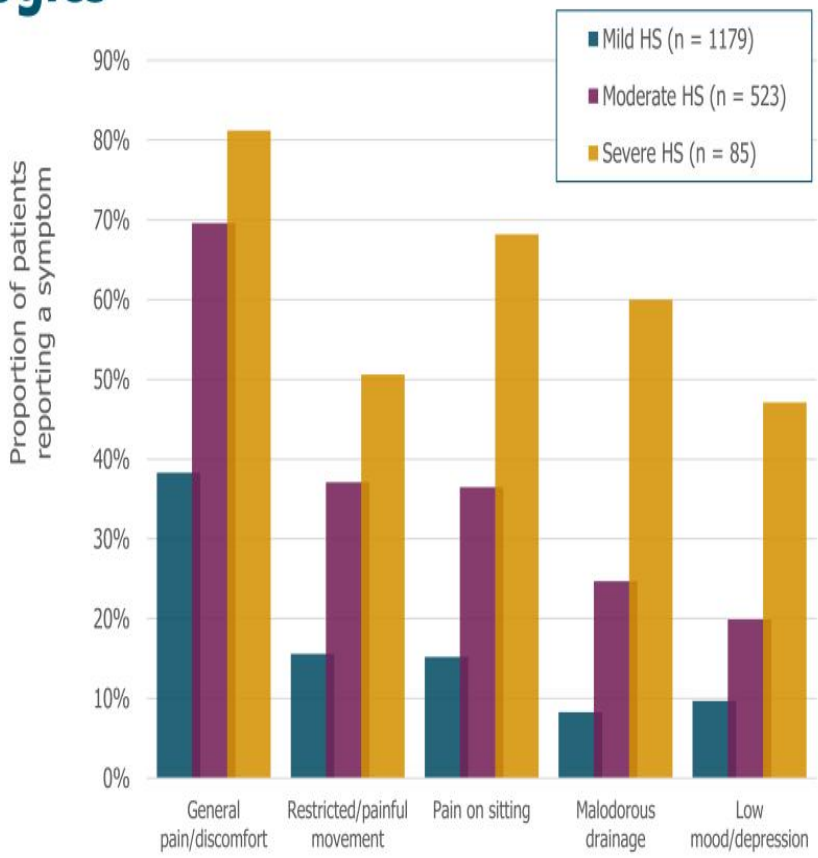
Areas commonly affected by HS include[4]:



Photos from Mendes-Bastos P, et al. *Front Med (Lausanne).* 2024;11:1403455; Ovadja ZN, et al. *Brit J Dermatol.* 2019;181:243-244; Cotter C, Walsh S. *Skin Health and Disease.* 2021;1(1):e7. CC-BY-4.0 License.
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

There is a Large Unmet Need in HS with a Majority of Patients Failing to Respond Adequately to anti-TNF and anti-IL-17 biologics

Severe Impact on Quality of Life:
A large proportion of patients still report significant and life-disrupting symptoms with existing treatment options[1,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.

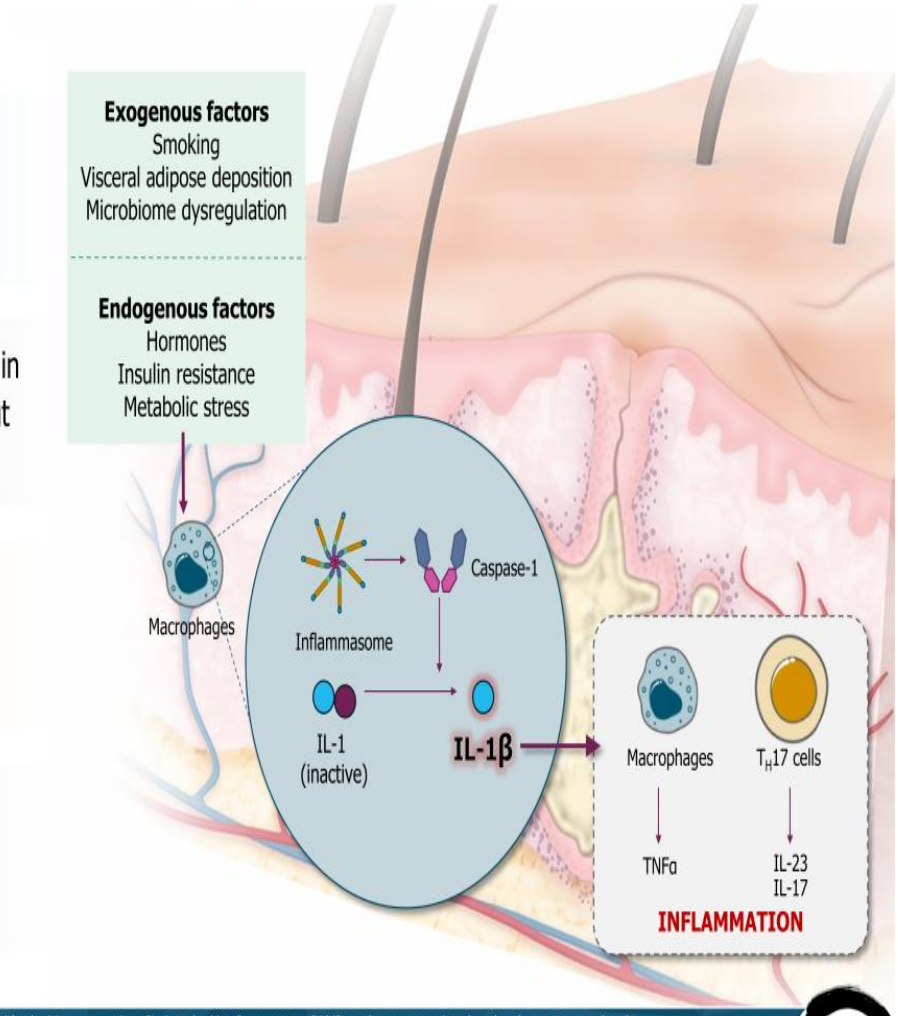
IL-1β Dominates the Pathophysiology of HS[1]

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 patients without HS[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]

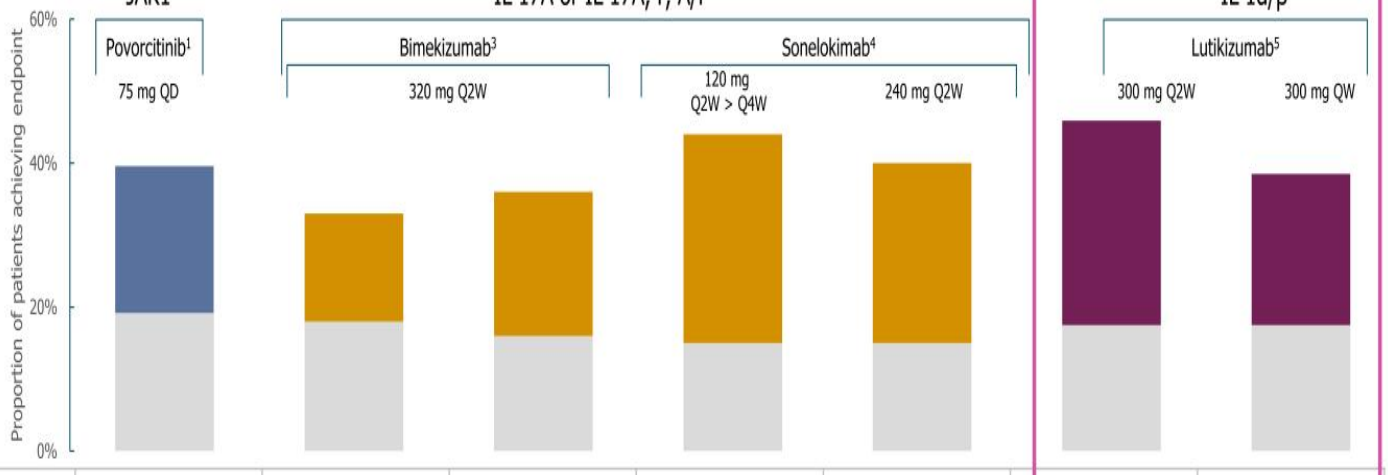


DAMP, damage-associated molecular pattern molecule; DC, dendritic cell; HS, hidradenitis suppurativa; IL, interleukin; R, receptor; PAMP, pathogen-associated molecular pattern molecule.
Figure adapted from Agnese ER et al. *Cureus.* 15(11):e49390. Creative Commons license, CC-BY 4.0.

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 Validates the Role for IL-1 in HS; Comparable Efficacy in a Refractory Population

HiSCR75

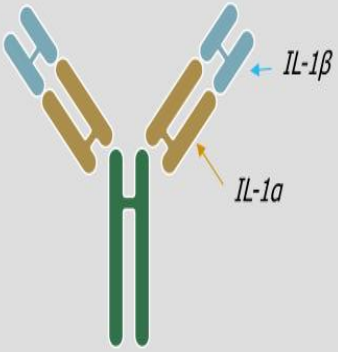
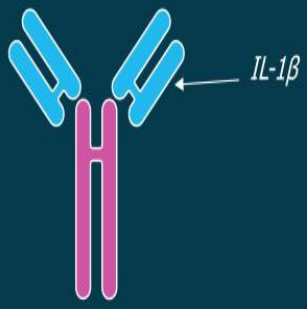


Trial	Phase 2	BE HEARD II	BE HEARD I	Phase 2	Phase 2	Phase 2	Phase 2
n/N	52/52	291/509	289/505	67/234	66/234	37/153	39/153
Time	12 wk	16 wk	16 wk	12 wk	12 wk	16 wk	16 wk

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

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. Kirby JS, et al. *JAAD.* 2024;90(3):P521-529; 2. Acelyrin Press Release. September 11, 2023. Accessed September 10, 2024. https://investors.acelyrin.com/news-releases/news-release-details/acelyrin-inc-announces-top-line-results-placebo-controlled; 3. Kimball AB, et al. *Lancet.* 2024;403(10443):2504-2519; 4. Kimball AB, Kirby B, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA; 6. Kimball AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

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

	Lutikizumab[1,2]	AVTX-009[3]
		
Specificity	IL-1 (α&β)	**IL-1β**
IL-1β K_D (pM)	44	**<3**
Subcutaneous bioavailability	46%	**73%**
Half-life	10-14 days	**19 days**
Dosing evaluated in HS study	Q1W & Q2W[4]	**Q2W & Q4W[5]**

K_D, 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.

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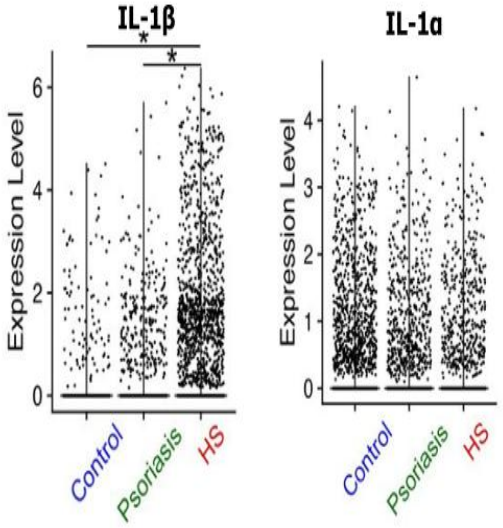
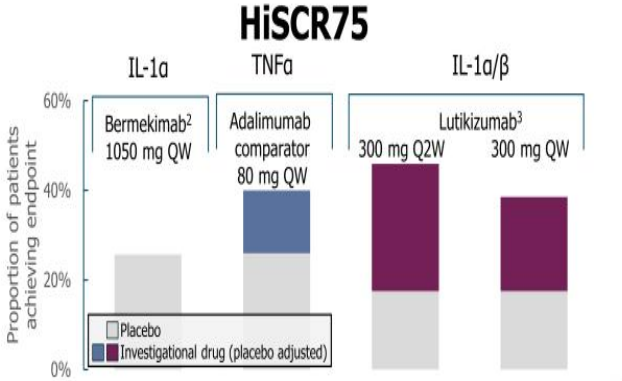
IL-1β is the Predominant Isoform that Drives Chronic Inflammation in HS

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



- IL-1β expression is higher in HS discharge than 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



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

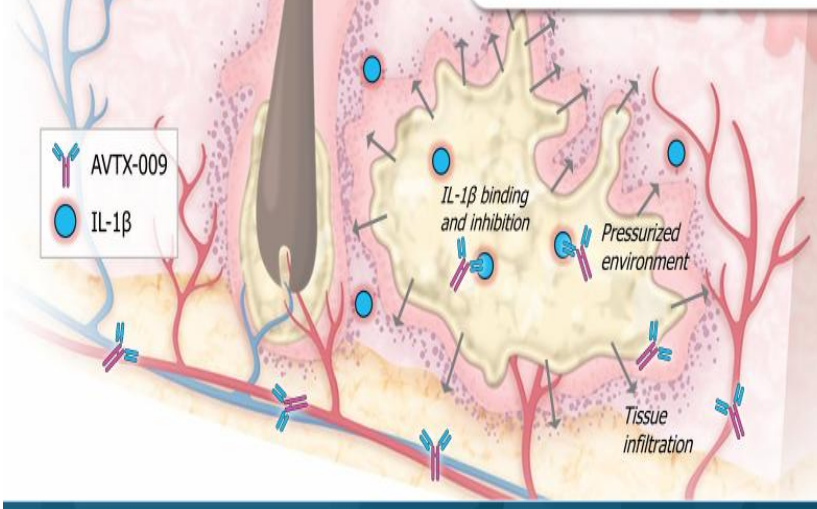
Focus on IL-1β blockade may lead to class leading efficacy

[a]Figure adapted from Kim JK et al. Creative commons license. CC-BY 4.0.
HiSCR, hidradenitis suppurativa clinical response; HS, hidradenitis suppurativa; IL, interleukin; mAb, monoclonal antibody; QW, weekly, Q2W, every other week; wk, week.
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.

AVTX-009: Affinity Matters in HS

Distribution of mAbs in tissue is an active process that is impacted by tissue structure, osmotic pressure, and affinity for target antigens[1]

Limited distribution of monoclonal antibodies to skin and into a pressurized environment means that higher doses may be required for dermatological conditions such as HS[2,3]



AVTX-009:
High affinity and specificity

Longer binding to the target

Higher accumulation into the tissue where it will be most effective

More inhibition of IL-1β with less antibody and potentially higher therapeutic 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.

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

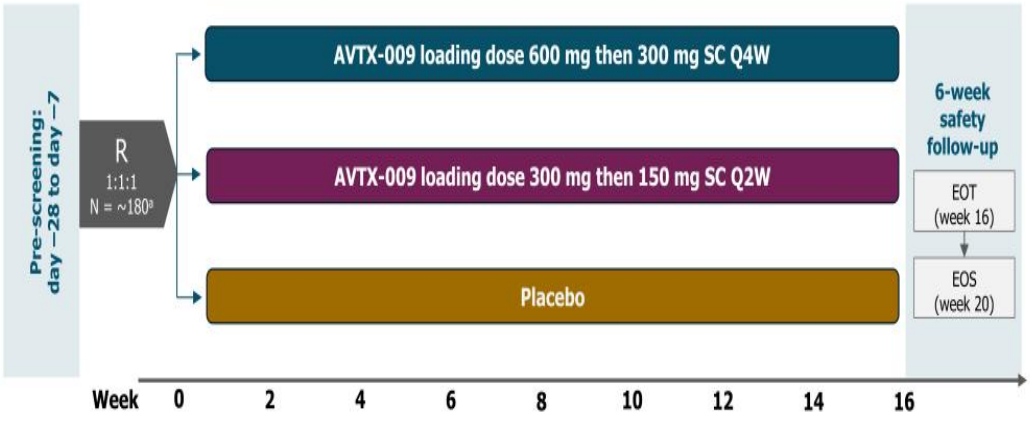
Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

Primary Study Endpoint

Primary Endpoint: Percentage of participants achieving HiSCR75 at 16 weeks

Key Inclusion Criteria

- HS for at least 6 months prior to baseline
- Total AN count of ≥5 at baseline
- HS lesions must be present in at least 2 distinct anatomic areas
- At least one HS lesion that is Hurley stage II or III
- Enrollment of patients who have not failed anti-TNF therapy (naive or exposed) will be capped at 40%



Key Secondary/Exploratory Endpoints

Key Secondary Endpoints:
- TEAEs
- HiSCR50, HiSCR90
- International HS Severity Score System (IHS4)
- AN count, draining fistula count
- Patient's Global Assessment of Skin Pain (PGA Skin Pain) (NRS30)
- Percentage of subjects with flares
- ADA

Exploratory Endpoints:
- PK
- HiSQOL, DLQI, PHQ-9
- Biomarkers:
  - CRP
  - IL-6
  - Potentially other biomarkers

[a]Trial has 80% power to show a HiSCR75 response for each individual arm (based on lutikizumab phase 2 HiSCR75).
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.

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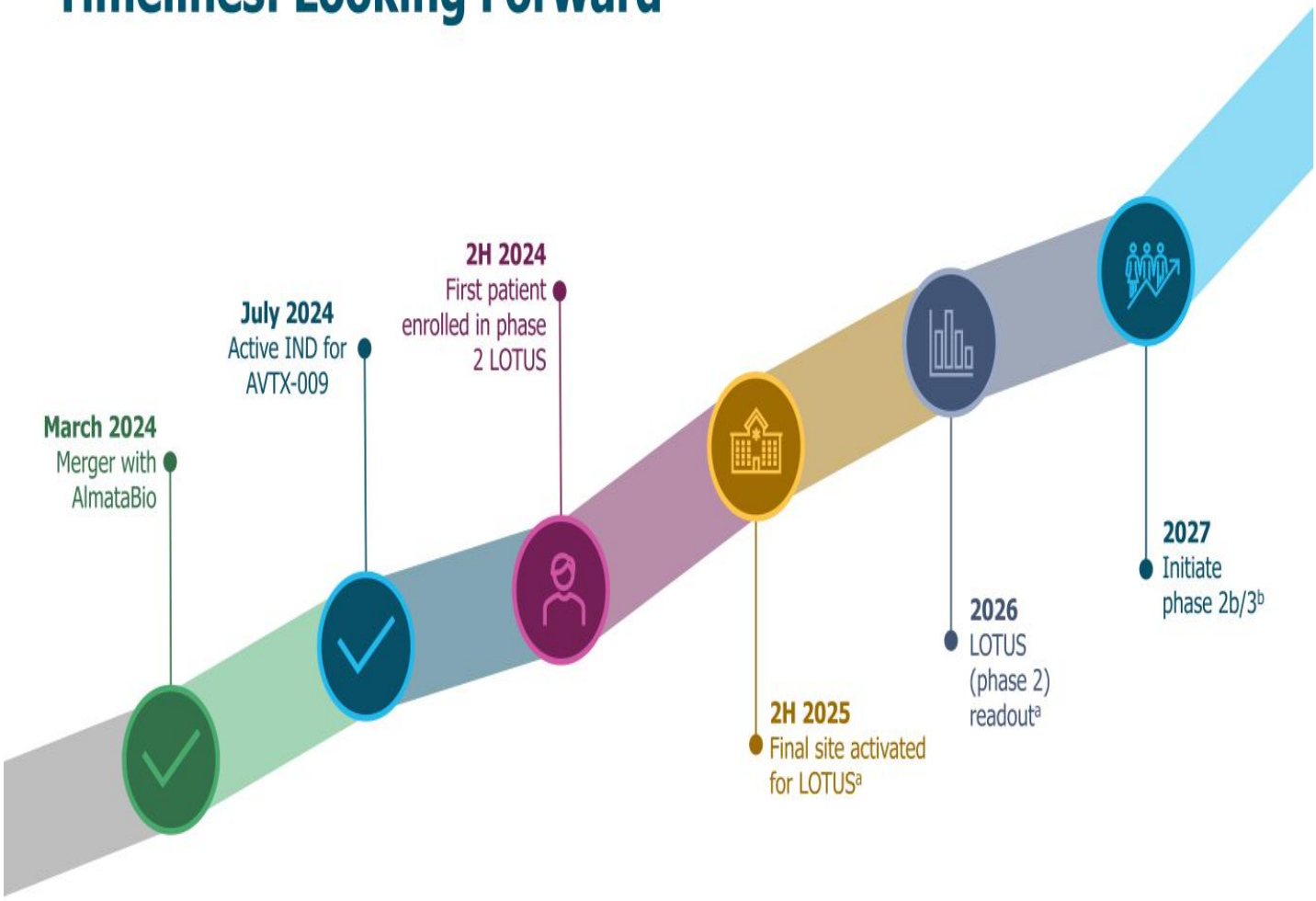
Diagnosed and Treated HS Population is Projected to Grow Substantially into a $10B+ Market by 2035[1]

	2023 *US Base Data*	2035 *US Projected*	MARKET DRIVERS
Overall HS prevalence[2]	**3.3 million**	**3.5 million** *(0.5% US population CAGR)*	**Potential Market Opportunity** Overall prevalence of HS of 3.3M expected to grow to 3.5M
HS diagnosed and treated[3]	**1.0 million**	**1.6 million** *(4% HS diagnosis CAGR)[a]*	**Total Addressable Market** Number of patients with HS diagnosed and treated will grow significantly from 30% to 45% of the total population, driven by new development and visibility with HCPs and patients
Moderate-to-severe HS[4]	**320,000**	**513,000**	**Segment Addressable Market** Increased recognition of disease leads to 60% growth of identified moderate to severe HS
Biologics treated[5]	**105,000** *(33% on biologics in 2023)*	**205,000** *(40% on biologics in 2030)[a]*	**Treated Addressable Market** New approvals will lead to more patients being treated with biologics, increasing from 30% to 40% share of segment (evidenced by the recent quickly growing use of Cosentyx in HS post-approval)

[a]HS diagnosis and treatment rates and biologic treatment rates are expected to increase over time.
CAGR, compound annual growth rate; HCP, healthcare provider; HS, hidradenitis suppurativa; US, United States.

1. HS Market Research 2024. Avalo Therapeutics Data on File; 2. Garg A, et al. *Am J Clin Dermatol.* 2023;24:977-990; 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



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

Broad Potential for Indication Expansion

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

Arthritis Indications

IL-1 targeting therapies are already approved in rheumatoid arthritis and for the treatment of acute gout flare[1,2]

Canakinumab data from Novartis's CANTOS study support the effect of IL-1β in reducing the incidence of total hip/total knee replacements in osteoarthritis patients with high systemic CRP[3]

There is scientific rationale for an anti-IL-1β therapeutic in additional arthritis indications

Inflammatory Bowel Disease

Dysregulated inflammasome activation has been implicated in the pathogenesis of Crohn's disease[4]

IL-1β is a key cytokine produced upon inflammasome activation

- IL-1– driven stromal–neutrophil interactions define a subset of patients who do not respond to current therapies[5,6]
- There is an observed overlap of patients that have IBD and HS[7,8]

Like HS, a large number of patients with IBD have suboptimal responses to current advanced therapy options

Additional Indications with Established Clinical Proof of Concept

The CANTOS study data support a role for anti-IL-1β in reducing the risk of major cardiovascular events in patients with previous myocardial infarction and elevated CRP[9]

IL-1 targeting therapies are also approved in periodic fevers, DIRA, Still's disease and recurrent pericarditis[1,2,10]

There are additional indications with supporting mechanistic and clinical rationales

Avalo is currently assessing additional indications for investment

CRP, C-reactive protein; DIRA, deficiency of interleukin receptor 1 antagonist; HS, hidradenitis suppurativa; IBD, inflammatory bowel disease.

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.

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Executive Summary

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Avalo Therapeutics: Developing Targeted Therapies for Immune Dysregulation

- Lead compound: AVTX-009 (anti-IL-1β mAb) has the potential for "best-in-disease" profile in hidradenitis suppurativa (HS)
  - Favorable POC validation in HS:
    - Abbvie's lutikizumab (IL-1α/β) demonstrated comparable efficacy to market leaders and pipeline therapeutics, and in a refractory population that had failed anti-TNF therapy
  - IL-1β (not IL-1α) is a dominant immunoregulator in HS, based on pre-clinical and clinical evidence
  - AVTX-009 has 15x higher affinity and a longer half-life than lutikizumab, potentially predictive of higher efficacy and more convenient dosing

Phase 2 LOTUS trial initiated with Topline data expected in 2026

HS is expected to grow to > $10B by 2035[1]

AVTX-009 has the potential to treat multiple immune-mediated diseases

Expected cash runway into at least 2027

IL, interleukin; IND, investigational new drug application; mAB, monoclonal antibody; MOA, mechanism of action.
1. HS Market Research 2024.

NASDAQ: AVTX

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Appendix

Avalo Capitalization and Cash Position

As of November 8, 2024		Number of shares
Common Stock	• Common shares outstanding[1]	10.5M
Assuming Conversion of Preferred Stock	• Preferred stock[1]	24.9M
Adjusted Share Count	• Adjusted common shares outstanding[1,2]	35.4M
Adjusted Market Capitalization	• Stock price	$13.31
	• **Adjusted market capitalization**	**$470.6M**

Cash of approximately $82 million as of September 30, 2024 with subsequent receipt of $69.4M of warrant exercise proceeds in 4Q 2024, provides expected runway into at least 2027

[1]Inclusive of share issuances from warrant exercises in 4Q 2024; [2]Does not include 2.6M stock options and restricted stock units outstanding resulting in a fully dilutive share count of 38M