
**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): **May 8, 2025**

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.)

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 May 8, 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:

<u>Exhibit No.</u>	<u>Description</u>
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: May 8, 2025

By: /s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer

Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

May 2025

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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 Mediated Inflammatory Diseases



Lead compound: AVTX-009 (anti-IL-1 β mAb) has the potential for "best-in-disease" profile in hidradenitis suppurativa (HS)

- Abbvie's lutikizumab (IL-1 α/β) demonstrated comparable efficacy to market leaders and pipeline therapeutics, and in a refractory population that had failed anti-TNF therapy
- IL-1 β (not IL-1 α) is a dominant 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 more convenient dosing⁴



Phase 2 LOTUS trial in HS initiated with Topline data expected in 2026



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



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. 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. 4. 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

200+ 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



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

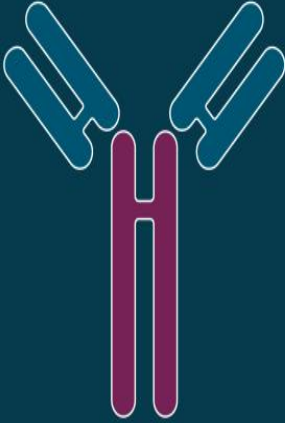


AVTX-009

A Highly Potent, Specific Inhibitor of IL-1 β

- Originally developed by Eli Lilly^{1,2}
- Stable 150 mg/mL dosage formulation³
 - 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 up to Q4W dosing in hidradenitis suppurativa and potentially a longer dosing interval in other indications

AVTX-009¹



<3 IL-1 β K_D (pM) Binding Affinity for IL-1 β
73% Subcutaneous Bioavailability
19-day Half-Life

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

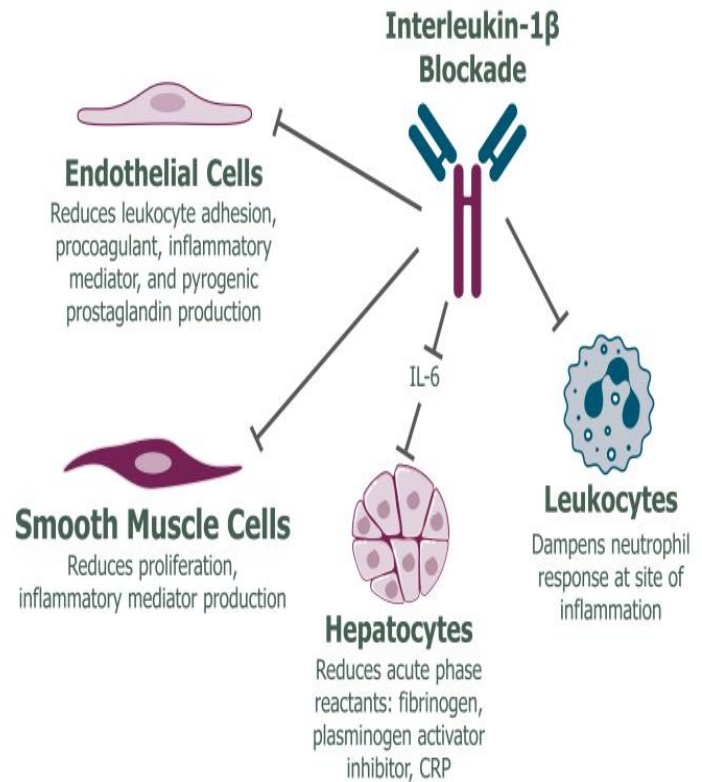
1. Bihorel S, et al. *AAAPS J*. 2014;16(5):1009-1017; 2. Sloan-Lancaster J, et al. *Diabetes Care*. 2013;36(8):2239-2246; 3. Data on file;

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>.

IL-1 β is a Master Regulator of Inflammation

- IL-1 β is a central driver of the inflammatory process¹ 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-1 β has been shown to be effective and safe in a variety of autoimmune and inflammatory diseases, including hidradenitis suppurativa¹⁻³
 - Well-established class safety and tolerability with 3 approved products targeting IL-1, >12,000 patients studied in clinical trials, and 13+ years real world experience⁴⁻⁷



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.

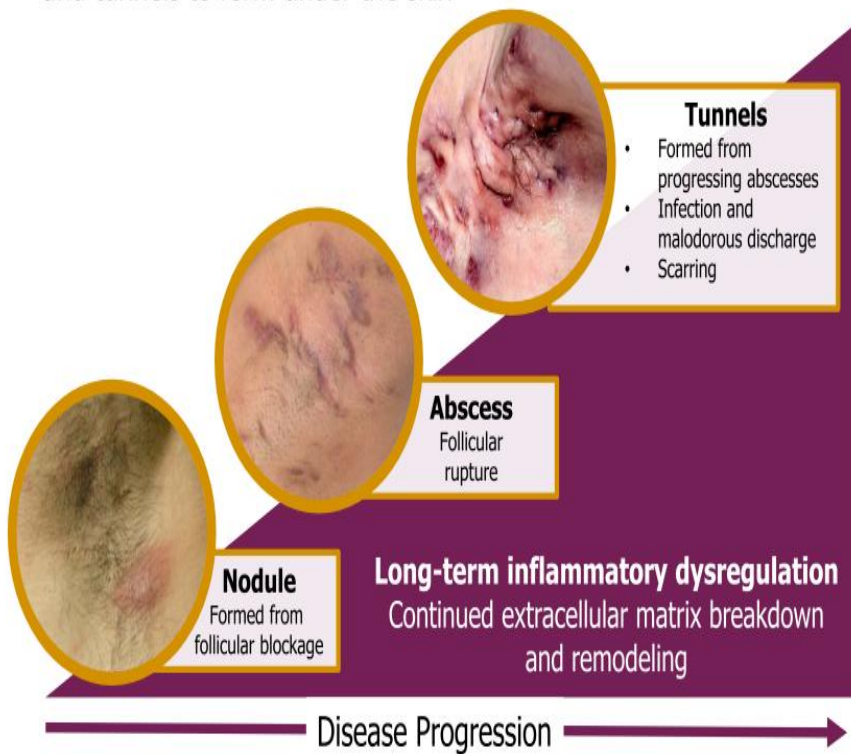
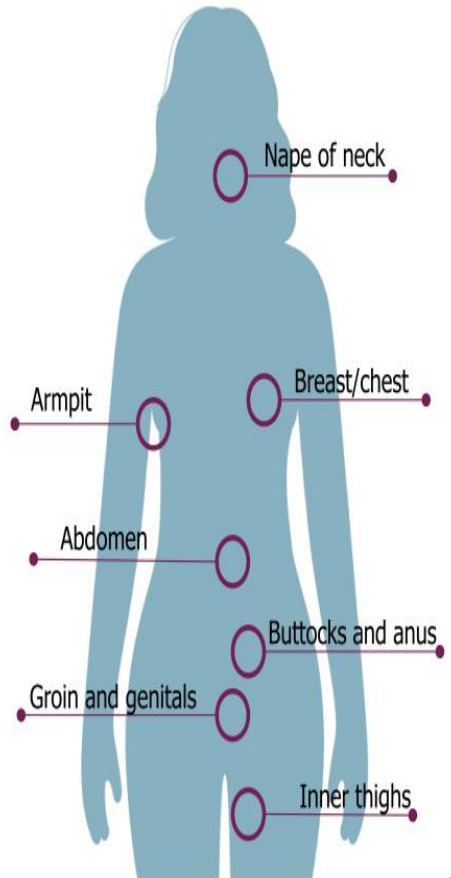
AVTX-009 Opportunity in Hidradenitis Suppurativa (HS)

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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 include⁴:



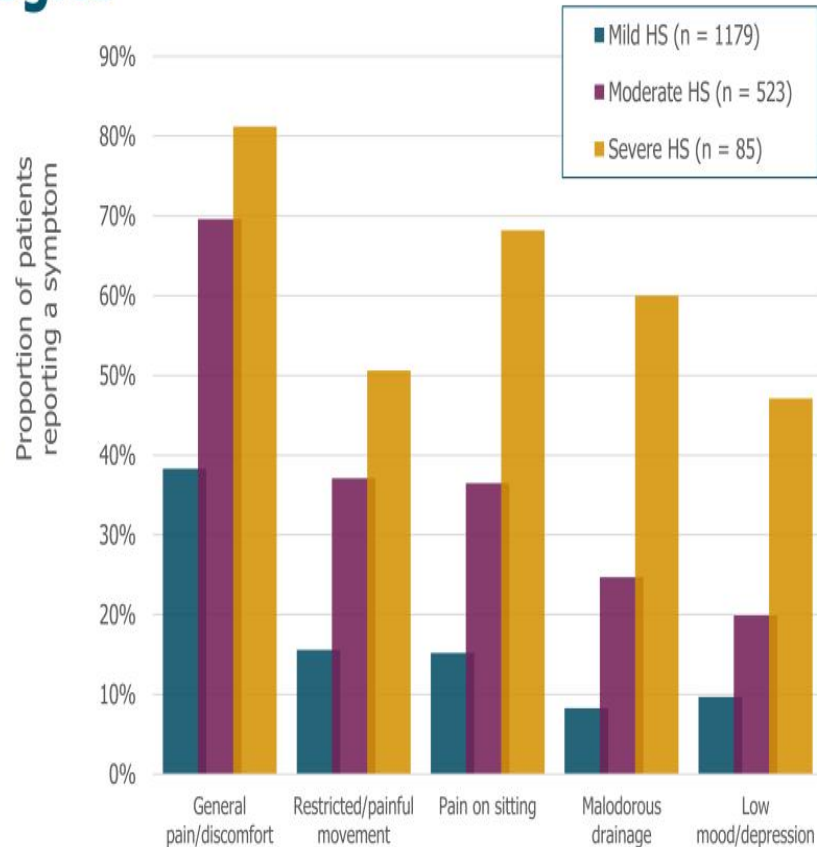
Photos from Mendes-Bastos P, et al. *Front Med (Lausanne)*. 2024;11:1403455; Ovardja ZN, et al. *Brit J Dermatol*. 2019;181:243-244; Cotter C, Walsh S. *Skin Health and Disease*. 2021;1(1):e7. CC-BY-4.0 License.

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^{1,2,a}



HS, hidradenitis suppurativa.

^aCurrent 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.

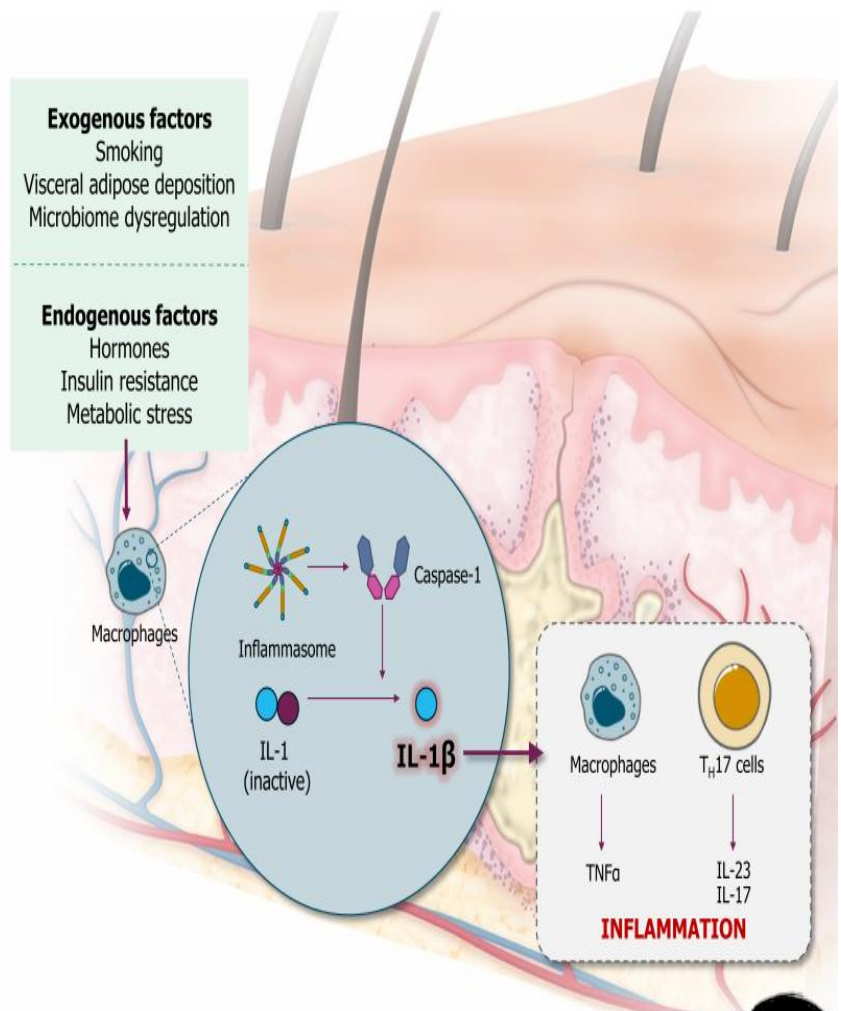
3 IL-1 β Dominates the Pathophysiology of HS¹

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



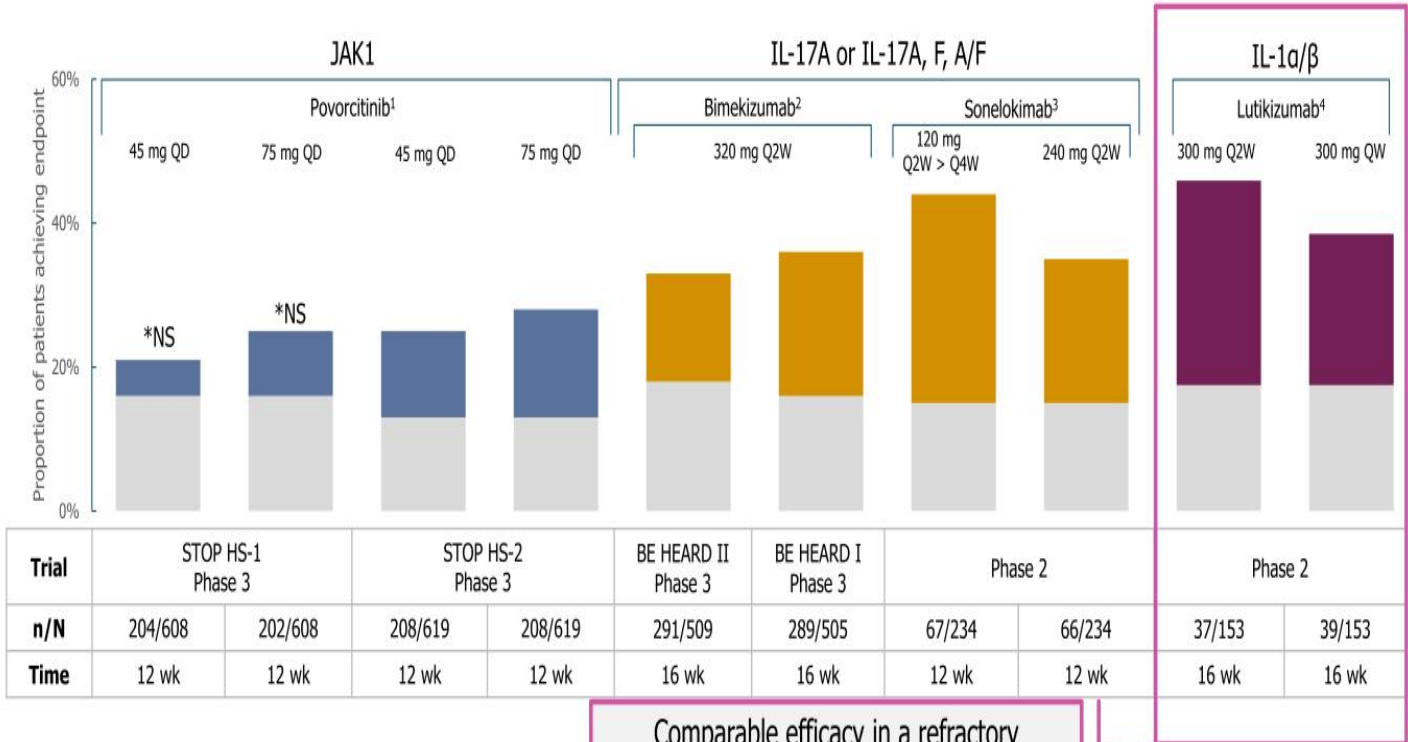
DAMP, damage-associated molecular pattern molecule; DC, dendritic cell; HS, hidradenitis suppurativa; IL, interleukin; R, receptor; PAMP, pathogen-associated molecular pattern molecule.

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

HiSCR75

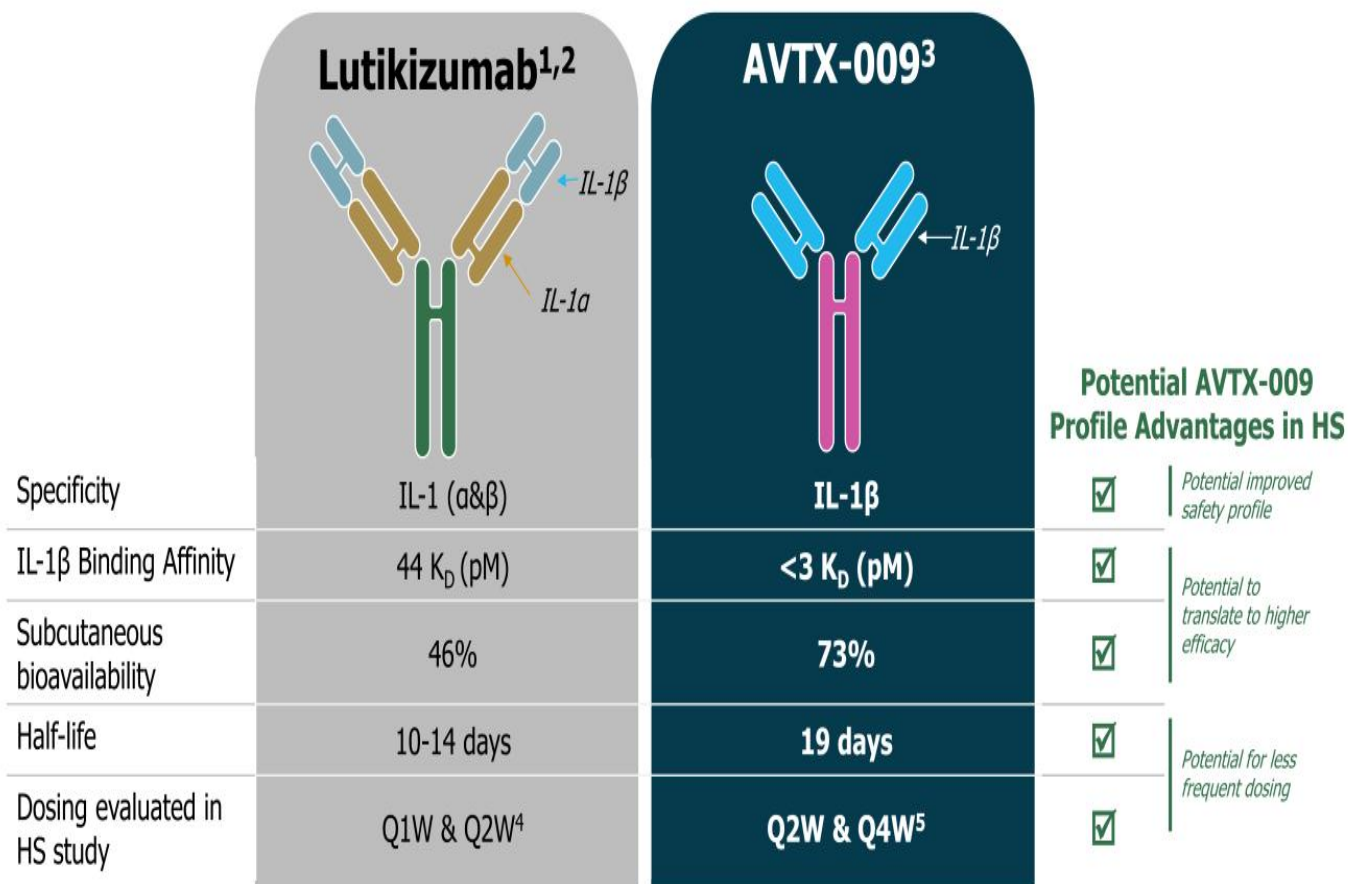


Comparable efficacy in a refractory population (71% Hurley stage III) that had already failed anti-TNF therapy

*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; 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-1 β Specificity, Higher Affinity, Bioavailability, and Longer Half-Life than Lutikizumab

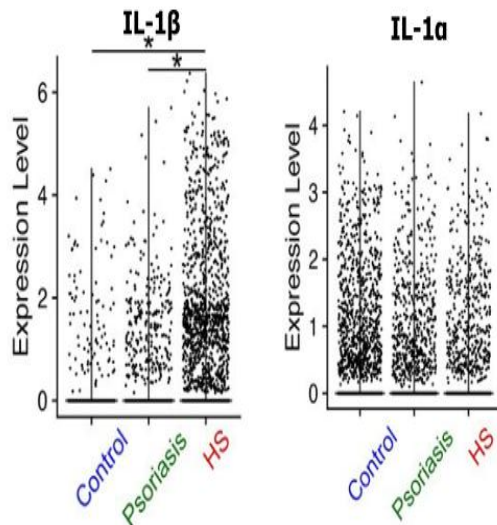


K_D, dissociation constant; pM, picomolar.

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.

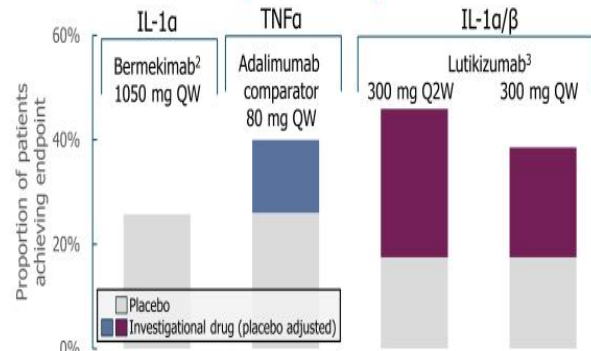
IL-1 β is the Predominant Isoform that Drives Chronic Inflammation in HS

IL-1 Expression in HS Skin^{1,a}



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

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



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

- Bermekimab, an IL-1 α specific mAb, performed no better than placebo in a Phase 2 study with adalimumab comparator arm^{1,2}
- Lutikizumab, an IL-1 α/β targeting mAb, demonstrated favorable efficacy vs placebo in a phase 2 trial

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

^aFigure 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.

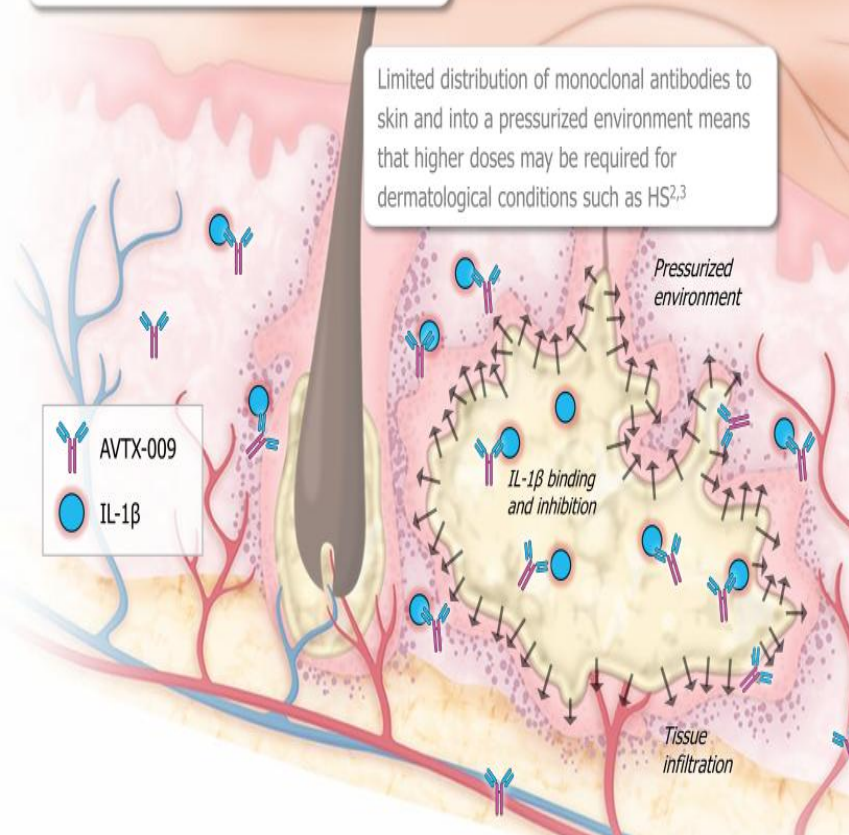
1. Kim JK, et al. *JACT* 2023;152:656-666; 2. ClinicalTrials.gov identifier: NCT04988308. Accessed September 5, 2024. <https://clinicaltrials.gov/study/NCT04988308>; 3. Kimball AB, Ackerman L, et al.

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 antigens¹

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

- ✓ The specificity of AVTX-009 for IL-1 β ensures it accumulates where it is most needed
- ✓ The superior affinity of AVTX-009 for IL-1 β is expected to cause the mAb to accumulate in the skin of HS patients, where IL-1 β expression is high^{1,4}
- ✓ Higher concentrations of AVTX-009 in the skin and high affinity lead to more and longer binding of IL-1 β and **higher potency** and **potentially superior 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)

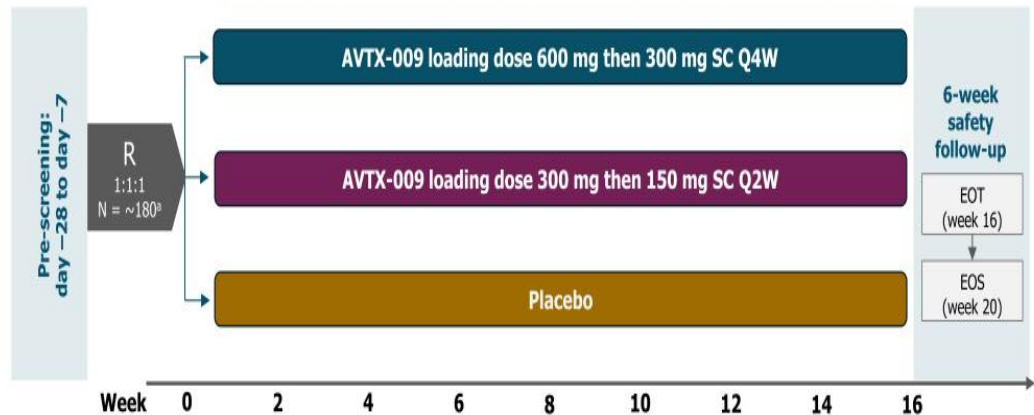
Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

Primary Study Endpoint

Primary Endpoint: Percentage of participants achieving HiSCR75 at 16 weeks

Key Inclusion Criteria

- HS for 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 $\sim 40\%$



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

^aTrial 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.

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

2023

US Base Data

2035

US Projected

MARKET DRIVERS

Overall HS prevalence²

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 treated³

1.0 million

1.6 million

(4% HS diagnosis CAGR)³

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 HS⁴

320,000

513,000

Segment Addressable Market

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

Biologics treated⁵

105,000

(33% on biologics in 2023)

205,000

(40% on biologics in 2030)³

Treated Addressable Market

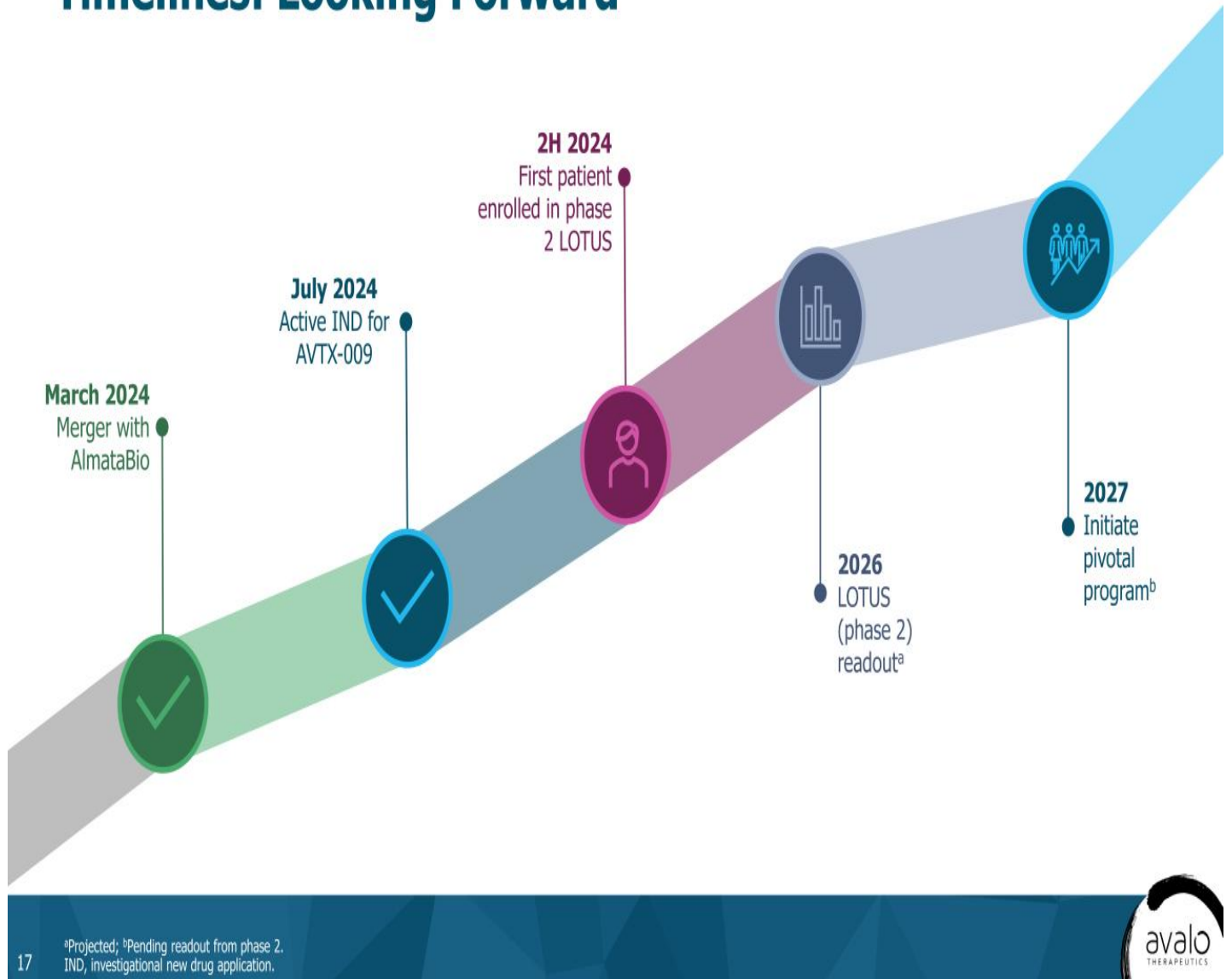
New approvals will lead to more patients being treated with biologics, increasing from 30% to 40% share of segment (evidenced by the recent quickly growing use of Cosentyx in HS post-approval)

³HS 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



Broad Potential for Indication Expansion

The logo for Avalo Therapeutics features a large, dark blue, brush-stroke style arc that curves from the top right towards the bottom left, partially enclosing the text. The text 'avallo' is in a lowercase, white, sans-serif font, with the 'o' being a simple circle. Below it, the word 'THERAPEUTICS' is written in a smaller, uppercase, white, sans-serif font.

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



IL-1 targeting therapies: approved in RA and acute gout flare^{1,2}

CANTOS study (Novartis): canakinumab data support the effect of IL-1 β in reducing total hip/total knee replacements in OA patients with high systemic CRP³

There is scientific rationale for an anti-IL-1 β in additional crystal-induced arthritis indications (including calcium pyrophosphate deposition disease)



IL-1 β is a key cytokine produced upon inflammasome activation, a process that appears to be dysregulated in Crohn's disease⁴

- IL-1 activity may 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



While not a current focus for Avalo, IL-1 targeting therapies have been approved in rare diseases including periodic fevers, DIRA, Still's disease and recurrent pericarditis^{1,2,10}

CANTOS study (Novartis): canakinumab data support anti-IL-1 β in reducing the risk of major CV events in patients with previous MI and elevated CRP⁹

There are additional indications with supporting mechanistic and clinical rationales

Avalo is currently assessing additional immunology indications for investment

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.



Executive Summary

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avallo
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Avalo Therapeutics: Developing Targeted Therapies for Immune Mediated Inflammatory Diseases



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NASDAQ: AVTX

www.avalotx.com

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avalotx
THERAPEUTICS

Appendix

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avallo
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Avalo Capitalization and Cash Position

As of March 31, 2025

Number of shares

Common Stock	• Common shares outstanding ^{1,2}	10.8M
	• Preferred stock ²	24.7M
<hr/>		
Adjusted Share Count	• Adjusted common shares outstanding ^{1,2}	35.5M
	• Stock price	\$8.01
Adjusted Market Capitalization	• Adjusted market capitalization	\$284.5M

Cash of approximately \$125 million as of March 31, 2025², provides expected runway into at least 2027

¹Does not include 4.3M stock options and restricted stock units outstanding resulting in a fully dilutive share count of 39.8M, ²Cash, common shares outstanding and preferred shares outstanding as of March 31, 2025 are preliminary, unaudited and subject to change

