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): October 8, 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 October 8, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in the Company's Phase 2 LOTUS Trial of AVTX-009 for the treatment of hidradenitis suppurativa. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

On October 8, 2024, 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 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated October 8, 2024.
99.2	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: October 8, 2024

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

Avalo Announces First Patient Dosed in Phase 2 LOTUS Trial of AVTX-009 for the Treatment of Hidradenitis Suppurativa

- *Global study in approximately 180 adults with hidradenitis suppurativa to assess the efficacy and safety of two dose regimens of AVTX-009 compared to placebo*
- *Topline data expected in 2026*

WAYNE, PA AND ROCKVILLE, MD, October 8, 2024 – Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced that the first patient has been dosed in the Company's Phase 2 LOTUS trial of AVTX-009 in hidradenitis suppurativa (HS). AVTX-009 is a humanized monoclonal antibody (IgG4) that binds to interleukin-1β (IL-1β) with high affinity and neutralizes its activity.

"The Avalo team has efficiently executed to achieve this important milestone and we are excited to have this trial underway. Hidradenitis suppurativa is a disease that can significantly impact quality of life and there is a need for improved treatment options. We believe AVTX-009's high potency could make it a best-in-class and best-in-indication treatment option for patients suffering from hidradenitis suppurativa," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"We look forward to releasing topline results in 2026."*

The LOTUS Trial is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two AVTX-009 dose regimens to evaluate the efficacy and safety of AVTX-009 in approximately 180 adults with moderate to severe hidradenitis suppurativa. Subjects will be randomized (1:1:1) to receive either one of two doses of AVTX-009 or placebo during a 16-week treatment phase. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Secondary objectives include but are not limited to: proportion of patients achieving HiSCR50 and HiSCR90 as well as change from baseline in: International HS Severity Score System (IHS4), draining fistula count, abscess and inflammatory nodule (AN) count and patients achieving at least a 30% reduction on a numerical rating scale in Patient's Global Assessment of Skin Pain (PGA Skin Pain). The number of patients with anti-drug antibodies, safety, and tolerability will be assessed. For additional information this trial (NCT06603077), please visit www.clinicaltrials.gov.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by painful nodules, abscesses, and tunnels that form in areas of the body such as the armpits, groin, and buttocks, severely impacting the quality of life of affected individuals.[1] HS is often underdiagnosed or misdiagnosed and therefore estimates of HS vary between 0.2-1.7% of the population worldwide.[2-5] The exact cause of HS is not fully understood but is believed to involve a combination of genetic, hormonal, and environmental factors. While advances in treatment have been made, limited treatment options are available. IL-1β plays a crucial role in the inflammatory cascade underlying HS, contributing to tissue damage, inflammation, and disease progression. Given the involvement of IL-1β in the inflammatory process of HS, we believe therapies that target IL-1β offer a potential treatment option for HS.

About AVTX-009

AVTX-009 is a humanized monoclonal antibody (IgG4) that binds to interleukin-1β (IL-1β) with high affinity and neutralizes its activity. IL-1β is a central driver in the inflammatory process. Overproduction or dysregulation of IL-1β is implicated in many autoimmune and inflammatory diseases. IL-1β is a major, validated target for therapeutic intervention. There is evidence that inhibition of IL-1β could be effective in hidradenitis suppurativa and a variety of inflammatory diseases in dermatology, gastroenterology, and rheumatology.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β mAb, targeting inflammatory diseases. Avalo also has two additional drug candidates, which include quisovalimab (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein). For more information about Avalo, please visit www.avalotx.com.

Forward-Looking Statements

This press release 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: drug development costs, timing of trials and trial results and other risks, including reliance on investigators and enrollment of patients in clinical trials; reliance on key personnel; regulatory risks; integration of AVTX-009 into our operations; 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.

References

[1]Patel ZS et al. Curr Pain Headache Rep. 2017;21(12):49.
[2]Egeberg A, et al. JAMA Dermatol 2016;152:429–34
[3]Phan K, et al Biomed Dermatol 2020; 4: 2-6
[4]Jfri, A, et al. JAMA Dermatol. 2021;157(8):924-31
[5]Nguyen TV, et al. J Eur Acad Dermatol Venereol. 2021;35(1):50-61

For media and investor inquiries:

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or

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ICR Westwicke
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339-970-2843

EXHIBIT 99.2

Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

October 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.

Executive Summary

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

- Clinically validated and derisked MOA
- Highly potent anti-inflammatory properties with favorable half-life that may allow for improved efficacy and convenient dosing
- Favorable safety profile

Phase 2 LOTUS trial initiated

- Topline Data expected 2026

HS is anticipated to become a $10B market

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

Expected cash runway into 2027

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

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

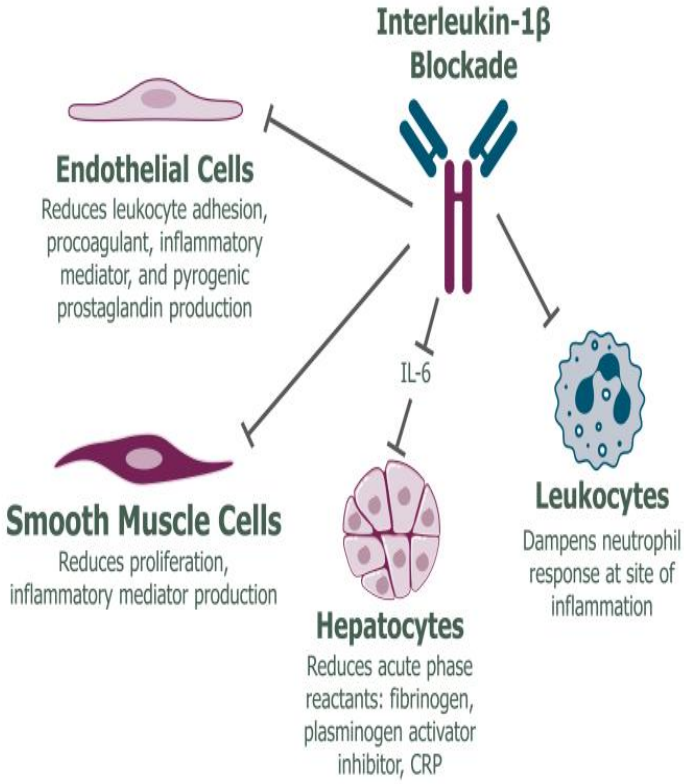
Colleen Matkowski
SVP, Global Regulatory Affairs,
Quality Assurance

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

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

IL-1β Is Increasingly Recognized as 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
  - IL-17
- IL-1β is involved in the pathogenesis of many autoimmune and autoinflammatory diseases
- Inhibition of IL-1β has been shown to be effective and safe in a variety of inflammatory diseases, including hidradenitis suppurativa[1-3]



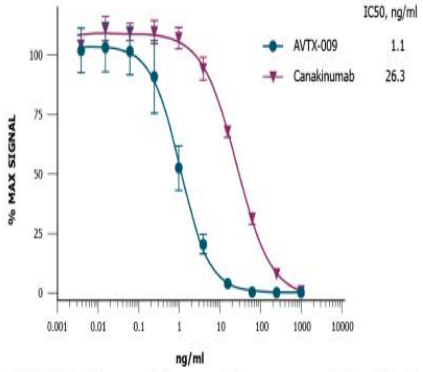
CRP, C-reactive protein; IL, interleukin; TNF, tumor necrosis factor.

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.

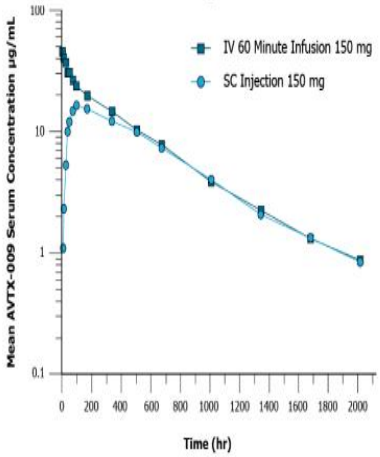
AVTX-009 Is a Highly Potent and Specific Inhibitor of IL-1β

- Originally developed by Eli Lilly[1,2]
- AVTX-009 exhibits superior potency compared to ILARIS® (canakinumab) in vitro
  - Higher affinity for IL-1β: K_D of <3 pM vs. 60 pM canakinumab[3]
- Stable 150 mg/mL dosage formulation[4]
  - Suitable for subcutaneous and intravenous administration
  - Initial presentation will be a prefilled syringe, post-approval plan to provide as an autoinjector
- Clinical experience: 245 patients studied in phase 1 and phase 2 trials[2,4-7]
  - Significant and rapid lowering of inflammatory biomarkers after a single dose in clinical trials
  - Excellent tolerability and safety at all doses up to 180 mg weekly
- Potency and half-life expected to support Q4W or less frequent dosing

AVTX-009 Has Higher Potency than Canakinumab



AVTX-009 Has a Strong Pharmacokinetic Profile



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. Chakraborty A, et al. *Clin Pharmacokinet.* 2012;51(6):e1-e18; 4. Data on file; 5. NCT04983732. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04983732; 6. NCT00942188. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT00942188; 7. NCT00380744. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT00380744.

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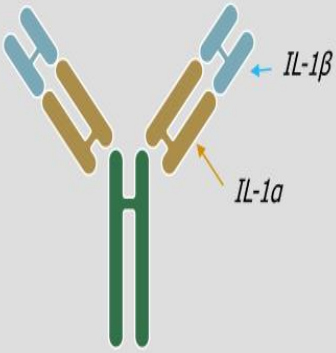
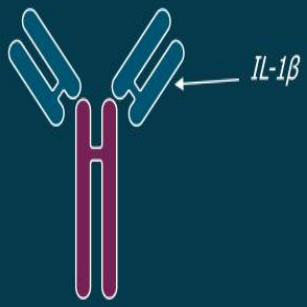
AVTX-009 Has High Affinity, High Bioavailability, and Long Half-Life

	Lutikizumab[1,2]	AVTX-009[3]
		
IL-1β K_D (pM)	21	**<3**
Subcutaneous bioavailability	46%	**73%**
Half-life	10-14 days	**19 days**

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.

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Hidradenitis Suppurativa (HS)

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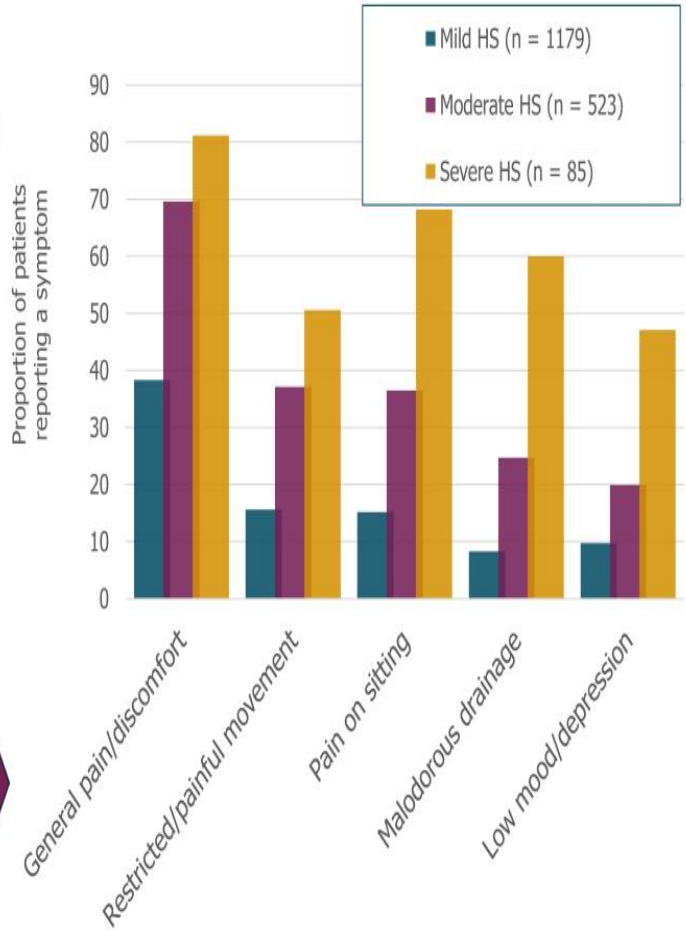
Hidradenitis Suppurativa: a Chronic Disease with a High Unmet Need

- Hidradenitis suppurativa is a chronic, often debilitating inflammatory skin disease that causes painful lumps, abscesses, and tunnels to form under the skin
- **Current treatments include:**
  - Antibiotics
  - Retinoids
  - Steroids
  - Cosentyx, Humira



Despite treatment, a large proportion of patients still report significant and life-disrupting symptoms[1]

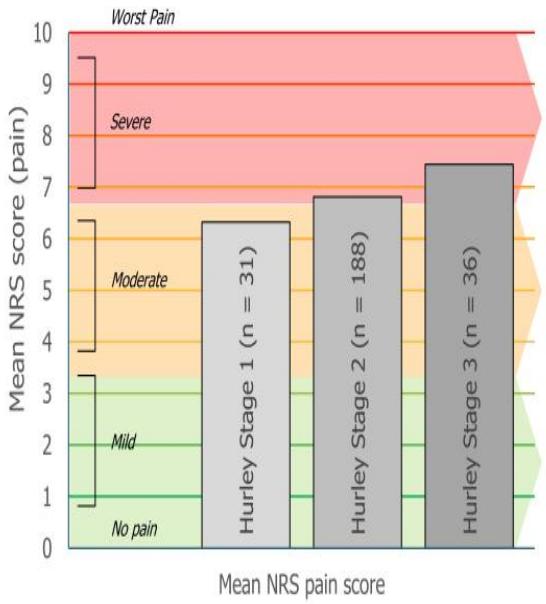
HS, hidradenitis suppurativa.

1. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605.

HS Causes Severe Pain and High Patient Burden

- Pain is a frequently overlooked aspect of HS[1,2]
- Even patients with "mild" disease report high levels of pain[3,4]
- This pain interferes with everyday life, sleep, and even movement[2]
- IL-1β blockade has been shown to reduce pain in multiple inflammatory conditions[5]

Mean Pain Scores by Disease Stage[3,4]



Areas commonly affected by HS include[2]:

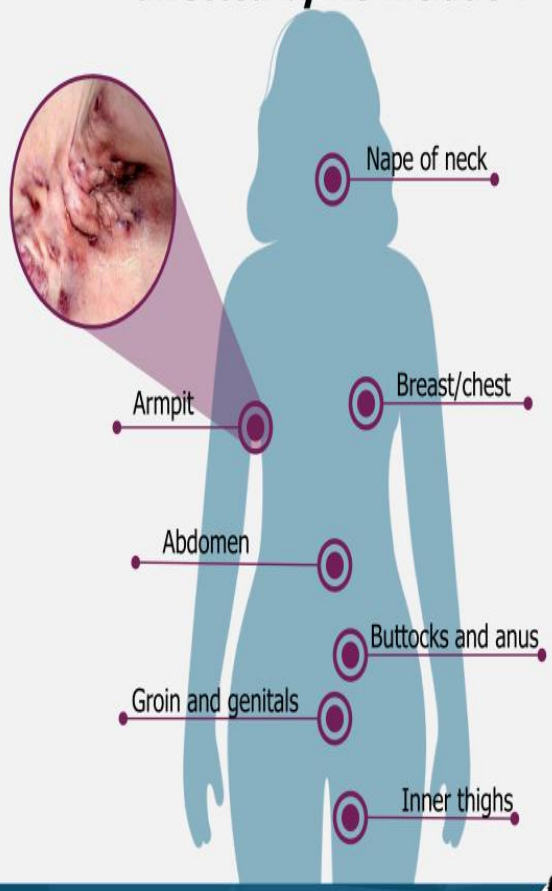


Photo from Cotter C, Walsh S. *Skin Health and Disease.* 2021;1(1):e7. CC-BY-4.0 License.
HS, hidradenitis suppurativa; IL, interleukin.

1. Johnston L, et al. *J Cutaneous Med Surg.* 2023;27(5):487-492; 2. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605; 3. Kimball AB, et al. *Dermatol Ther.* 2024;14:83-98; 4. Grimstad Ø, et al. *J Eur Acad Dermatol Venereol.* 2019;33(6):1164-1171; 5. Ren K, Torres R. *Brain Res Rev.* 2009;60(1):57-64.

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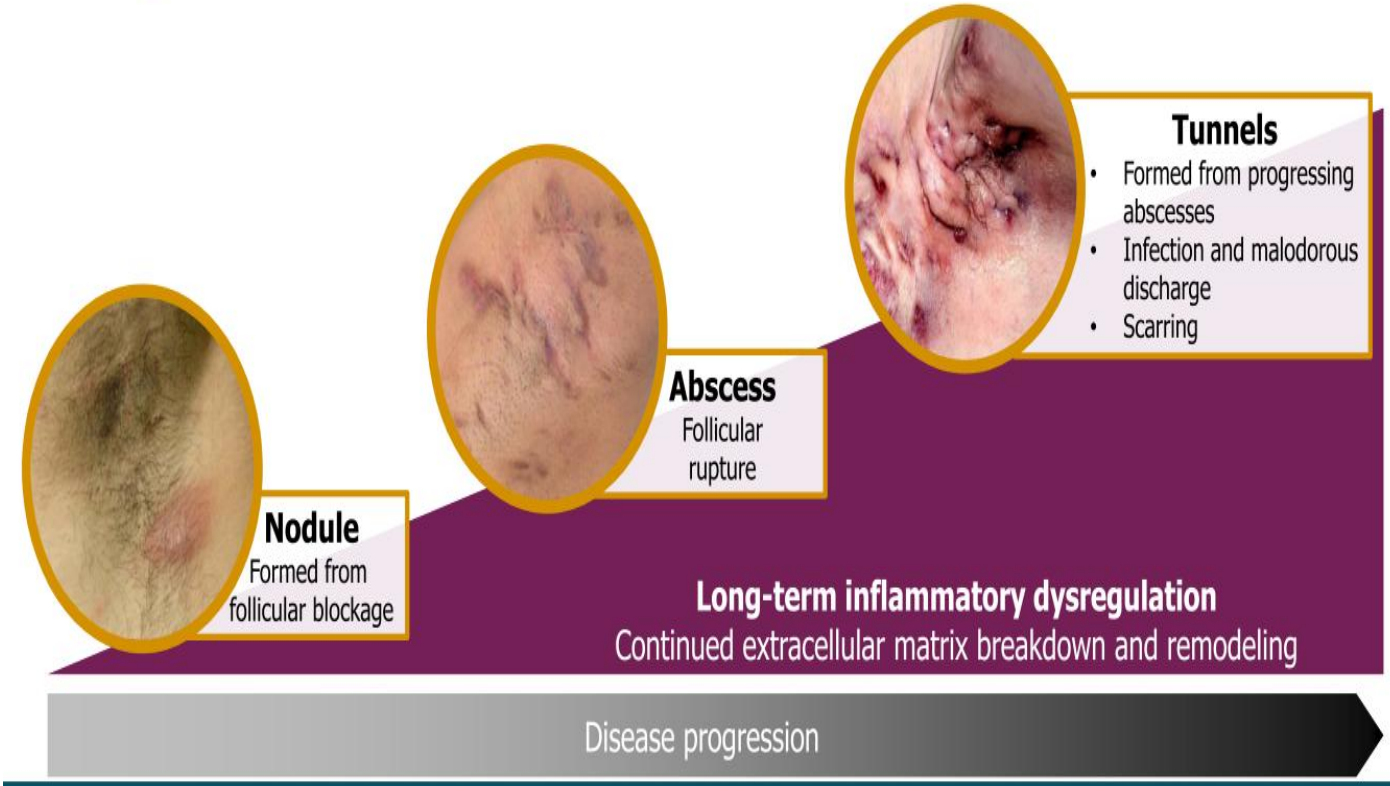
Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction



Hidradenitis suppurativa patients need a potent and targeted anti-inflammatory treatment

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.

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Diagnosed and Treated HS Population is Projected to Grow Substantially into a $9.5B+ 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
Receiving biologics[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 given 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.

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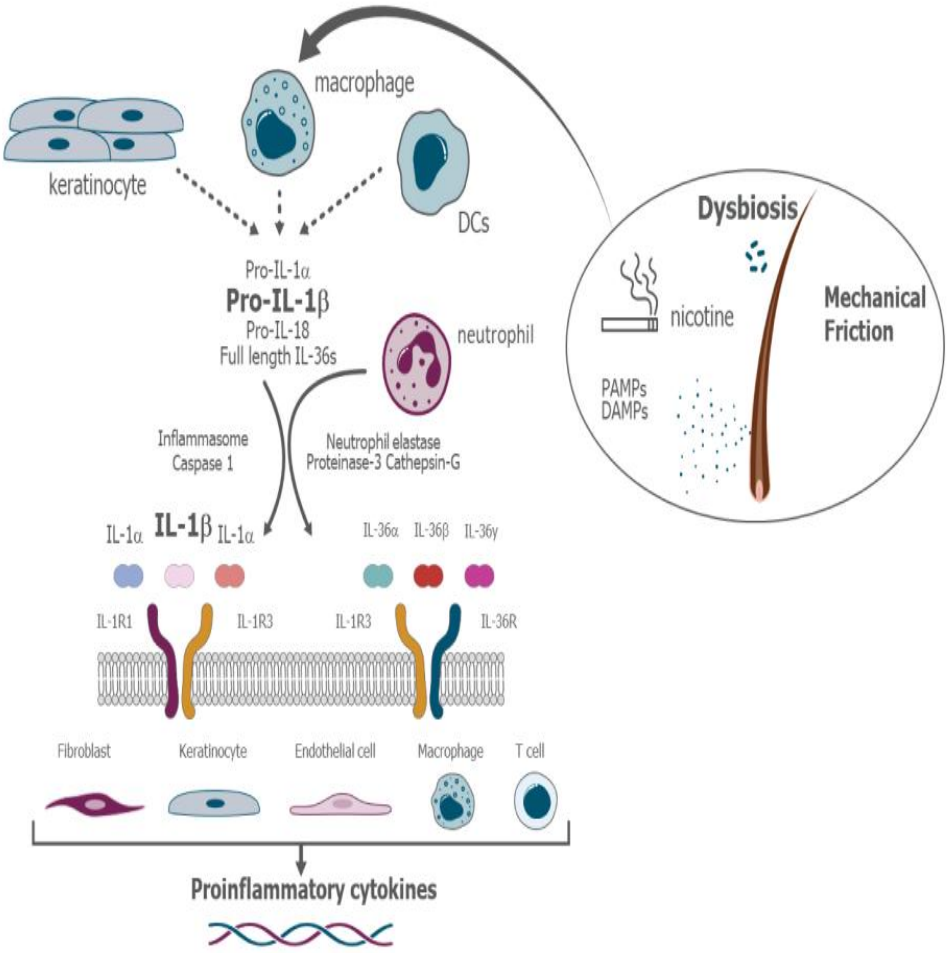
IL-1β is Strongly Implicated in the Pathophysiology of HS[1]

- The inflammatory cascade in HS is triggered by various external stimuli including:
  - Smoking
  - Dysbiosis
  - Mechanical stress
- IL-1β is a key driver of the inflammatory cascade that leads to the destruction of the pilosebaceous unit
- HS patients exhibit increased IL-1β levels in lesional skin[2,3]
- Clinical benefit for 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.

1. Calabrese L, et al. *Biomolecules*. 2024;14(2):175; 2. Vossen ARJV, et al. *J Invest Dermatol*. 2020;140(7):1463-1466.e2; 3. Kelly G, et al. *Br J Dermatol*. 2015;173(6):1431-1439; 4. Kimball AB, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

Hidradenitis Suppurativa Patients Often Have Other Comorbidities That Could Impact Treatment

Patients have a **~2-6x** increased risk of inflammatory bowel disease[1]

Patients have a **~2x** increased risk of myocardial infarction, acute embolism, or deep vein thrombosis[2]

Patients have a **~1.5x** increased risk of cancer (overall) and a **~2.6x** increased risk of cutaneous squamous cell carcinoma[3]

22-50% of patients are obese and nearly **1 in 3** have diabetes[2,3]

1. Chen WT, Chi CC. *JAMA Dermatol.* 2019;155(9):1022-1027; 2. Krajewski PK, et al. *Int J Dermatol.* 2024;63(6):799-805; 3. Abu Rached N, et al. *Ann Med.* 2024;56(1):2382372; 4. Garg A et al. *Am J Clin Dermatol.* 2023; 24: 977–990; 5. Rinderknecht F-AB, Naik HB. *Int J Womens Dermatol.* 2024;10(1): e130.

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Warnings and Precautions in Commonly Used Immunologic Drugs

JAK1 Inhibitor[1]

- Serious infection
- Opportunistic infection
- Risk of malignancy
- Thrombosis
- Blackbox warning: All-cause mortality

Anti-TNF1[2]

- Serious infection
- Opportunistic infection
- Risk of malignancy
- Thrombosis

Anti-IL-17[3,4]

- Serious infection
- IBD exacerbation
- Suicidal ideation (Bimzelx)

Anti-IL-1β[5]/IL-1[6,7]

- Serious infection
- Opportunistic infection (isolated cases with Ilaris)

HS, hidradenitis suppurativa; IBD, inflammatory bowel disease; IL, interleukin; JAK1, janus kinase 1; MOA, mechanism of action; TNF, tumor necrosis factor.

1. Rinvoq. Package insert. AbbVie Inc.; 2024; 2. Humira. Package insert. AbbVie Inc.; 2024; 3. Cosentyx. Package insert. Novartis Pharmaceuticals Corporation; 2024; 4. Bimzelx. Package insert. UCB Inc.; 2023; 5. Ilaris. Package insert. Novartis Pharmaceuticals Corporation; 2023; 6. Arcalyst. Package insert. Kiniksa Pharmaceuticals (UK), Ltd.; 2021; 7. Kineret. Package insert. Swedish Orphan Biovitrum AB; 2000.

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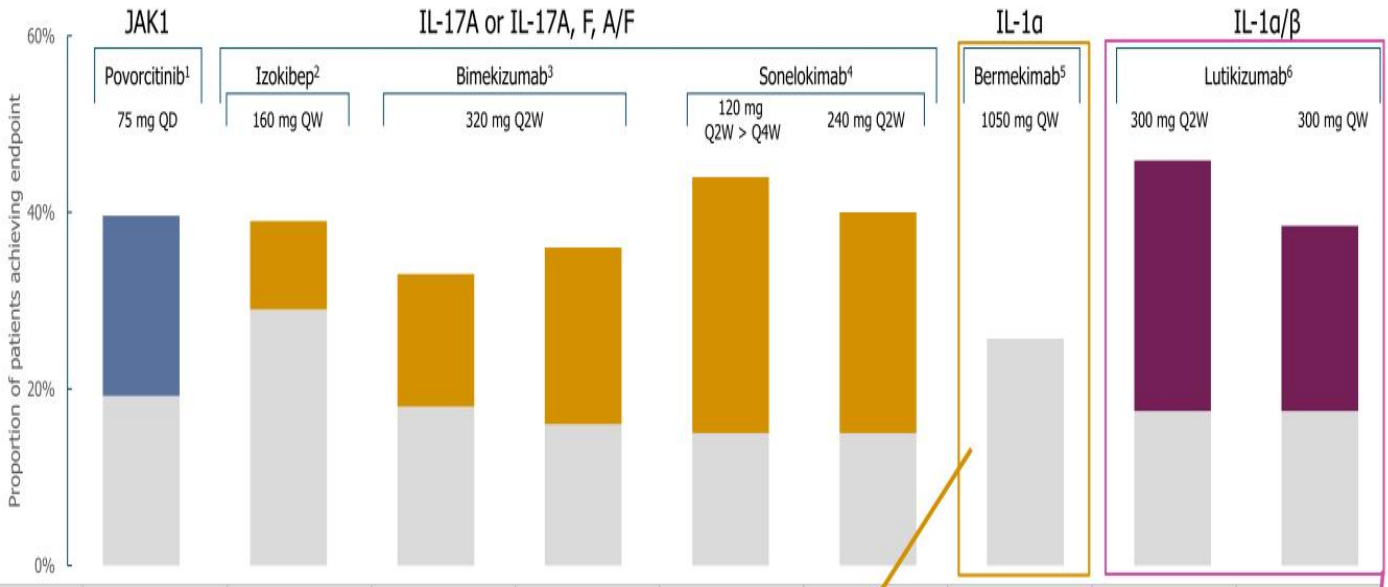
Previous Clinical Trials Validate and Derisk Our MOA

HiSCR75



Trial	Phase 2	Phase 2B/3	BE HEARD II	BE HEARD I	Phase 2	Phase 2	Phase 2 interim analysis	Phase 2	Phase 2
n/N	52/52	57/175	291/509	289/505	67/234	66/234	35/70	37/153	39/153
Time	12 wk	16 wk	16 wk	16 wk	12 wk	12 wk	16 wk	16 wk	16 wk

Placebo
Investigational drug (placebo adjusted)

Failure in phase 2 validates focusing on IL-1β

Comparable efficacy in a sicker population (65%-74% 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; 5. ClinicalTrials.gov identifier: NCT04988308. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04988308; 6. Kimball AB, Ackerman L, et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

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

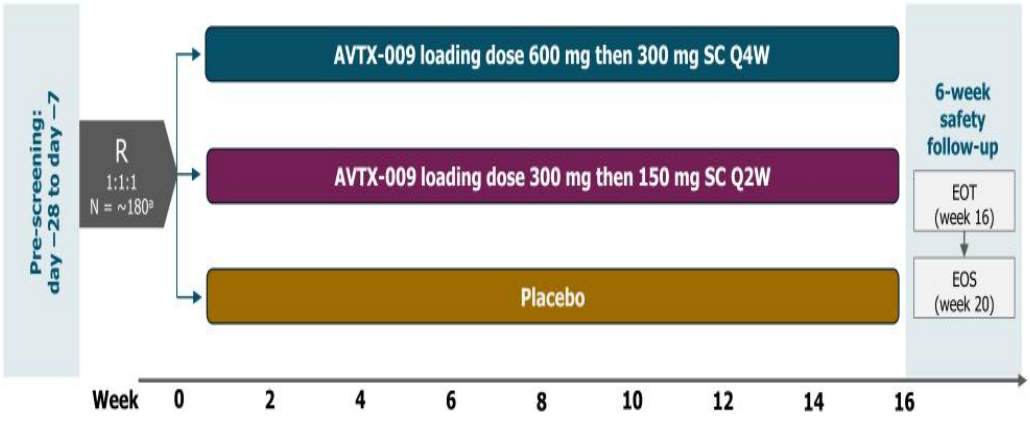
Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

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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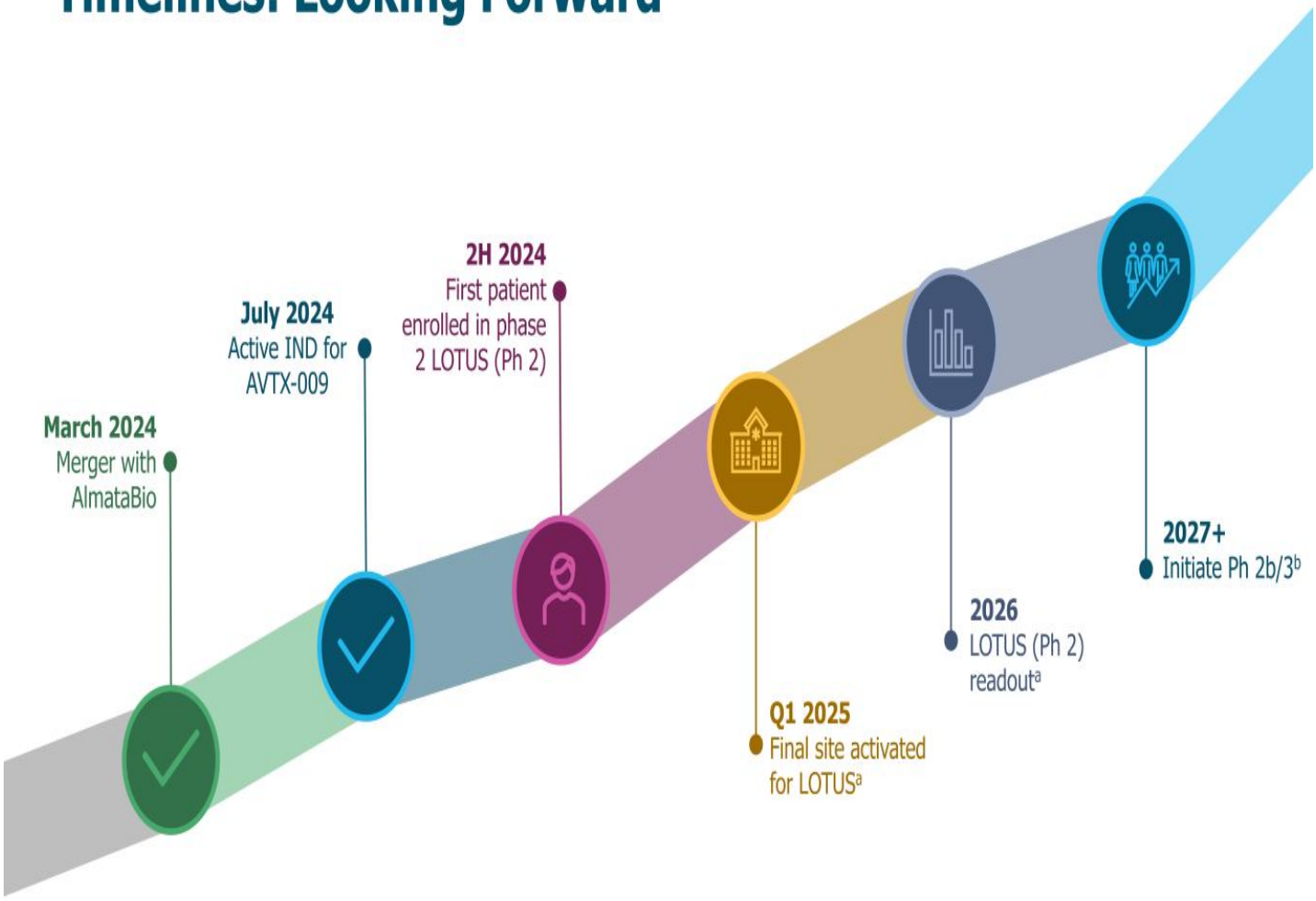
Timelines: Looking Forward

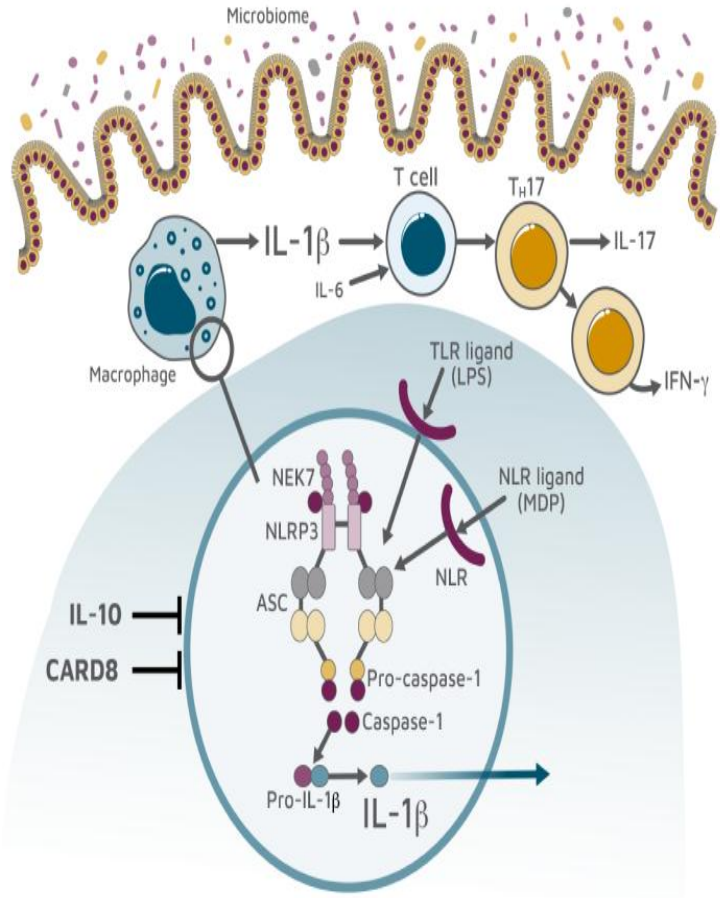


[a]Projected; [b]Pending readout from phase 2.
IND, investigational new drug application.

Potential Additional Indications

Role of IL-1β in IBD

- IL-1β plays a central role in inflammation in IBD[1]
  - IL-1β is a key cytokine produced upon inflammasome activation
  - Dysregulated inflammasome activation has been implicated in the pathogenesis of Crohn's disease
- IL-1–driven stromal–neutrophil interactions define a subset of patients who do not respond to current therapies[2,3]
- There is an observed overlap of patients that have IBD and HS[4,5]



HS, hidradenitis suppurativa; IBD, inflammatory bowel disease.

1. Mao L, et al. *Front Immunol.* 2018;9:2566; 2. Friedrich M, et al. *Nat Med.* 2021;27(11):1970-1981; 3. Cader MZ, Kaser A. *Nat Med.* 2021;27(11):1870-1871; 4. Chen WT, Chi CC. *JAMA Dermatol.* 2019;155(9):1022-1027; 5. Zhang M, et al. *World J Clin Cases.* 2021;9(15):3506-3516.

Recent IL-1 Trial Initiations in IBD

- The goal of IBD therapeutics is remission, yet only a minority of IBD patients obtain remission with current therapies
- AbbVie is currently conducting studies to evaluate lutikizumab, a dual variable domain IL-1α/1β antagonist as monotherapy in ulcerative colitis and in combination with Skyrizi in Crohn's Disease

> "...we believe lutikizumab has the potential to be used in combinations to provide transformational levels of efficacy in IBD. We plan to evaluate combo approaches with lutikizumab and Skyrizi...in Crohn's. Our Phase 2 studies in IBD are expected to begin later this year."
>
> - Roopal Thakkar, MD
> SVP, Global Therapeutics
> Chief Medical Officer
> *AbbVie 4Q23 Earnings Call Transcript*

There is an opportunity for greater efficacy for patients with IBD with AVTX-009 as a monotherapy and in combination with anti-IL-23

IBD, inflammatory bowel disease; UC, ulcerative colitis.

Executive Summary

Executive Summary

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

- Clinically validated and derisked MOA
- Highly potent anti-inflammatory properties with favorable half-life that may allow for improved efficacy and convenient dosing
- Favorable safety profile

Phase 2 LOTUS trial initiated

- Topline Data expected 2026

HS is anticipated to become a $10B market

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

Expected cash runway into 2027

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

NASDAQ: AVTX

www.avalotx.com

Appendix

Avalo Capitalization

As of August 13, 2024		Number of shares
Common Stock	• Common shares outstanding[1]	9.7M
Assuming Conversion of Preferred Stock and Exercise of Warrants	• Preferred stock[1]	13.7M
	• Warrants issued on March 28, 2024[2]	12.0M
Adjusted Share Count[3]	• Adjusted common shares outstanding[3]	35.4M
Adjusted Market Capitalization	• Stock price[4]	$9.88
	• **Adjusted market capitalization**	**$349.4M**

[1]8.6M shares of preferred stock automatically converted to common stock subject to beneficial ownership limitations on August 13, 2024, the date of Avalo's Annual Stockholder Meeting; [2]The warrants are exercisable for ~$5.80 per underlying share of common stock and expire on the earlier of (i) the fifth anniversary of the date of issuance or (ii) the thirty-first day following the public announcement of the first patient dosed in a Phase 2 trial of AVTX-009 in hidradenitis suppurativa; [3]Does not include 2.6M stock options and restricted stock units outstanding resulting in a fully dilutive share count of ~38M; [4]Reported closing price of our common stock on August 13, 2024