# 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): November 12, 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 November 12, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing that the Company has received $69.4 million in gross proceeds from the full exercise of the warrants issued in a March 2024 private placement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

As of November 8, 2024, Avalo has 10,463,633 shares of common stock outstanding and 24,895.92 shares of Series C Preferred Stock outstanding. Each share of Series C Preferred Stock is convertible into 1,000 shares of common stock, subject to beneficial ownership limitations.

On November 12, 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 November 12, 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: November 12, 2024

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

# Avalo Therapeutics Receives $69.4 Million in Proceeds from the Full Exercise of Private Placement Warrants

- *Proceeds from the full exercise of warrants issued in the first quarter of 2024 private placement bring the total gross proceeds from the transaction to $185 million*
- *Cash runway expected into at least 2027*

**WAYNE, PA AND ROCKVILLE, MD, November 12, 2024** – Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company focused on the treatment of immune dysregulation, today announced that it has received $69.4 million in gross proceeds from the full exercise of the warrants issued in a March 2024 private placement.

*"We appreciate the outstanding support of our investors by fully exercising their warrants from the private placement earlier this year. While our primary focus remains on the execution of our Phase 2 LOTUS trial in hidradenitis suppurativa, we are excited to expand the AVTX-009 program into additional inflammatory indications,"* said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"We are hard at work identifying our next indication, the launch and execution of which will benefit from our improved cash position and extended cash runway."*

The warrants were issued as part of the private placement in March 2024 that was led by Commodore Capital and TCGX, with participation from BVF Partners, Deep Track Capital, OrbiMed, Petrichor, and RA Capital Management. 11,967,526 warrants were issued and all have been exercised at an exercise price of $5.796933 per underlying share of common stock, resulting in gross proceeds to Avalo of $69.4 million and the issuance of 781,259 shares of common stock and 11,186.267 shares of series C non-voting convertible preferred stock. As of November 8, 2024, Avalo has 10,463,633 shares of common stock outstanding and 24,895.92 shares of series C preferred stock outstanding. Each share of series C preferred stock is convertible into 1,000 shares of common stock, subject to certain beneficial ownership limitations.

**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.

**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 the LOTUS Trial**

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

dosing regimens 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.

**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: the intended use of proceeds from the warrant exercise; 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**:

Christopher Sullivan, CFO
Avalo Therapeutics, Inc.
ir@avalotx.com
410-803-6793

*or*

Meru Advisors

Lauren Glaser
lglaser@meruadvisors.com

EXHIBIT 99.2

# Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

November 2024

avalo THERAPEUTICS

# 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 at least 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

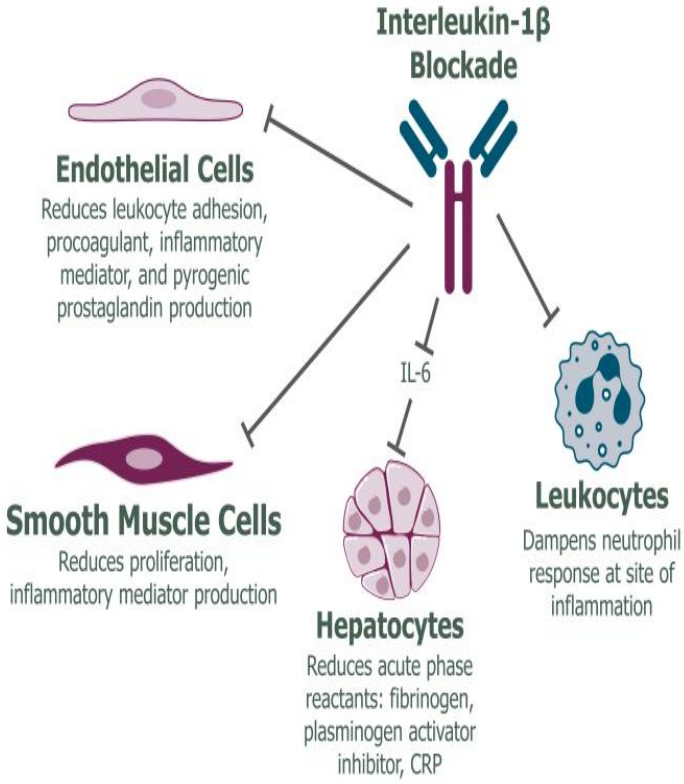
**Colleen Matkowski**
SVP, Global Regulatory Affairs,
Quality Assurance

**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]





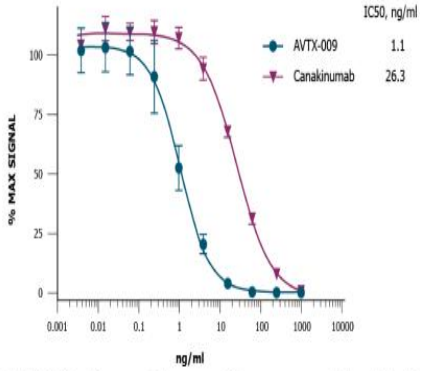

CRP, C-reactive protein; IL, interleukin; TNF, tumor necrosis factor.

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.

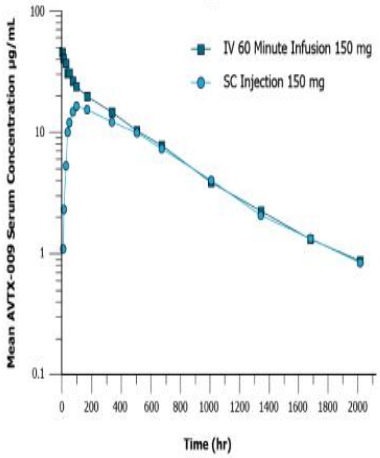
# AVTX-009 Is a Highly Potent and Specific Inhibitor of IL-1β

- 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**



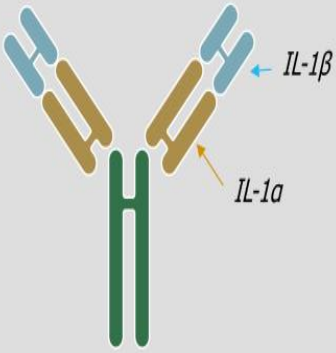
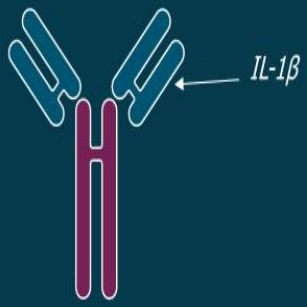

**AVTX-009 Has a Strong Pharmacokinetic Profile**




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.

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

| | Lutikizumab[1,2] | AVTX-009[3] |
|---|---|---|
| |   |   |
| IL-1β $K_D$ (pM) | 44 | **<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.



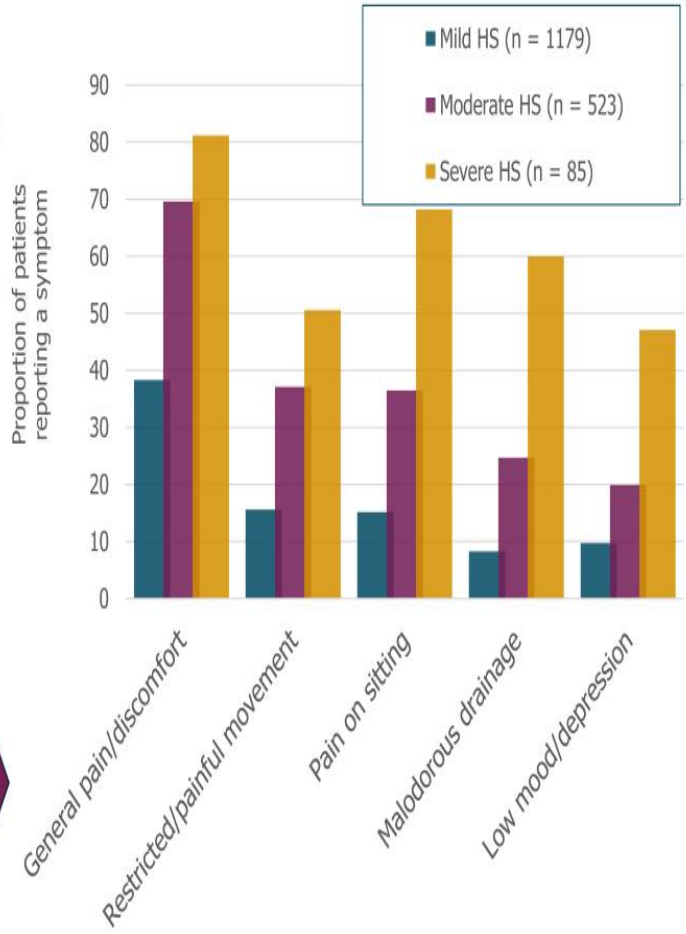

avalo THERAPEUTICS

# Hidradenitis Suppurativa (HS)

avalo THERAPEUTICS

# 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.

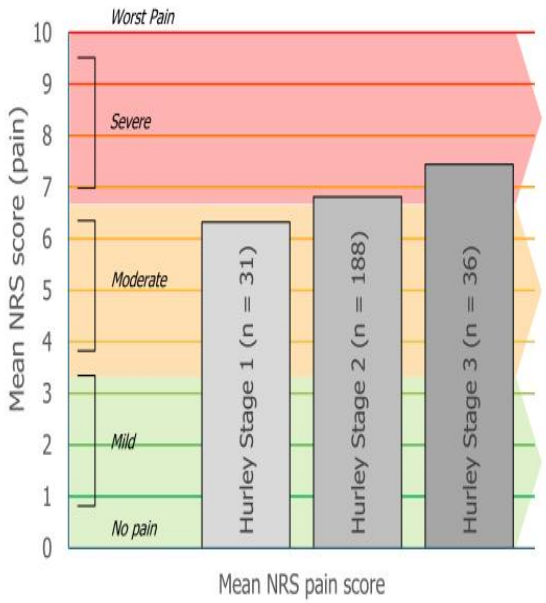
1. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605.

avalo THERAPEUTICS

# 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]:**

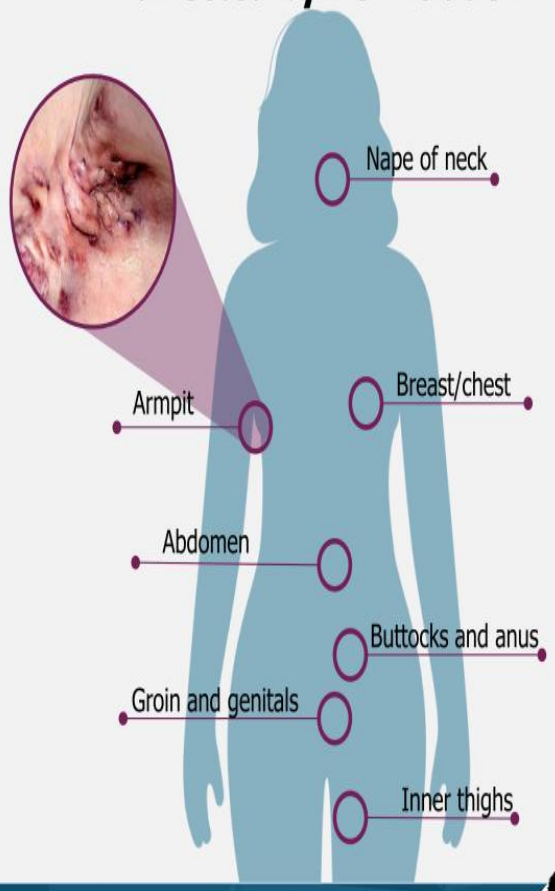
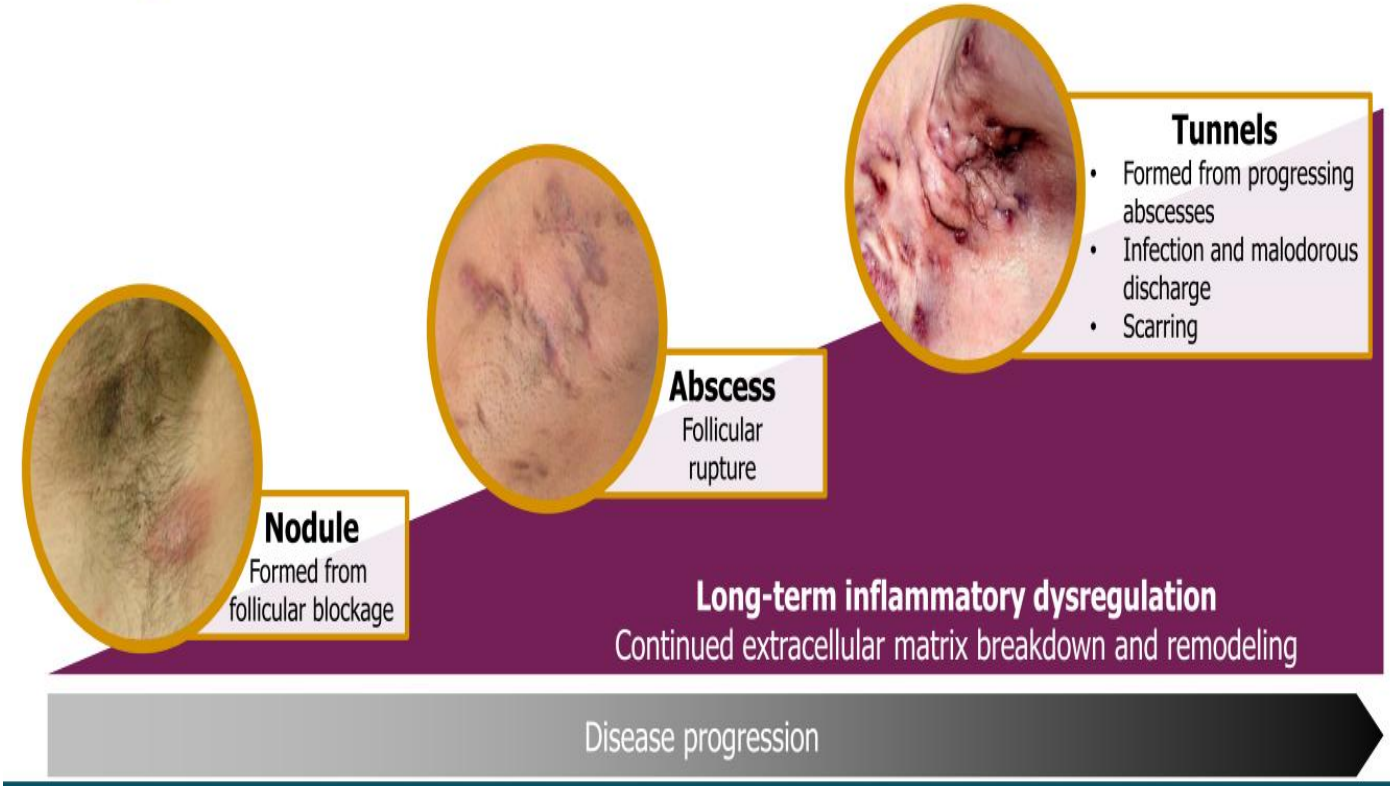



Photo from Cotter C, Walsh S. *Skin Health and Disease.* 2021;1(1):e7. CC-BY-4.0 License.
HS, hidradenitis suppurativa; IL, interleukin.

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.

# Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction




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



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.

avalo THERAPEUTICS

# 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.

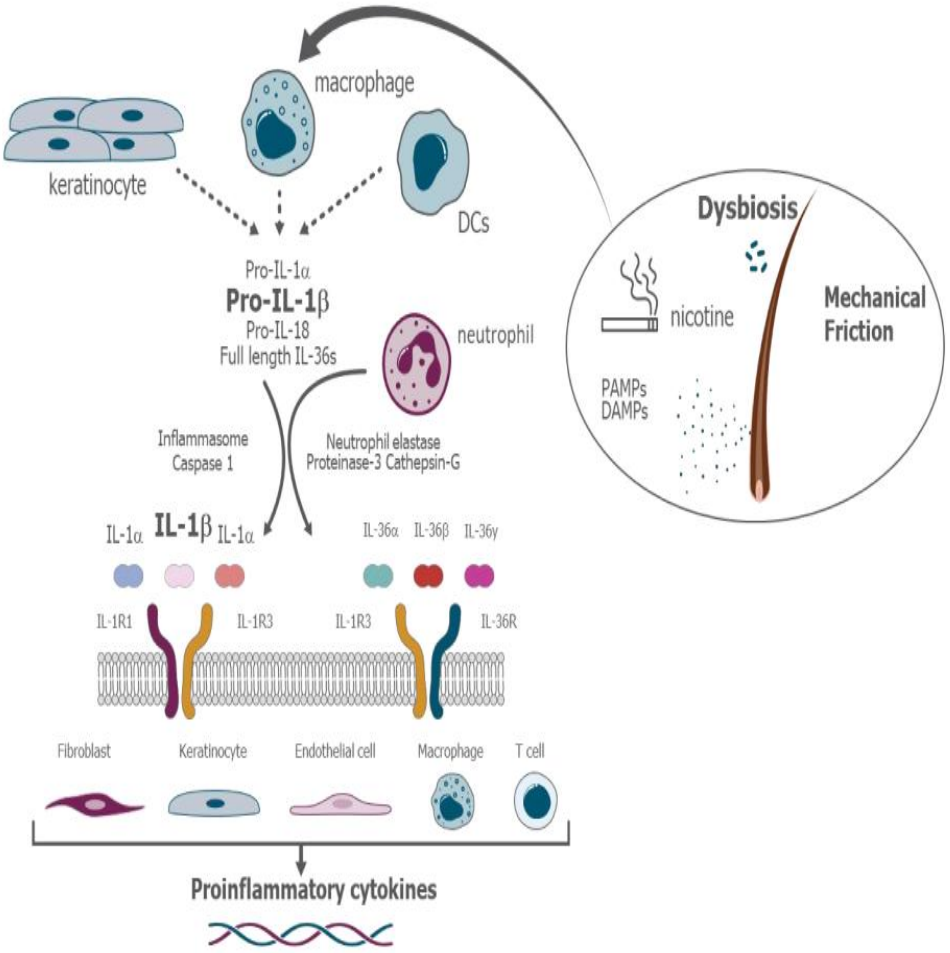
1. HS Market Research 2024. Avalo Therapeutics Data on File; 2. Garg A, et al. *Am J Clin Dermatol.* 2023;24:977-990; 3. Garg AX, et al. *Dermatol Ther.* 2022;3:581-594; 4. Ingram JR, et al. *J Eur Acad Dermatol Venereol.* 2022;36(9):1597-1605; 5. Rinderknecht FB, Naik HB. *Int J Womens Dermatol.* 2024;10(1):e130.



avalo THERAPEUTICS

# 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

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.

avalo THERAPEUTICS

# 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)



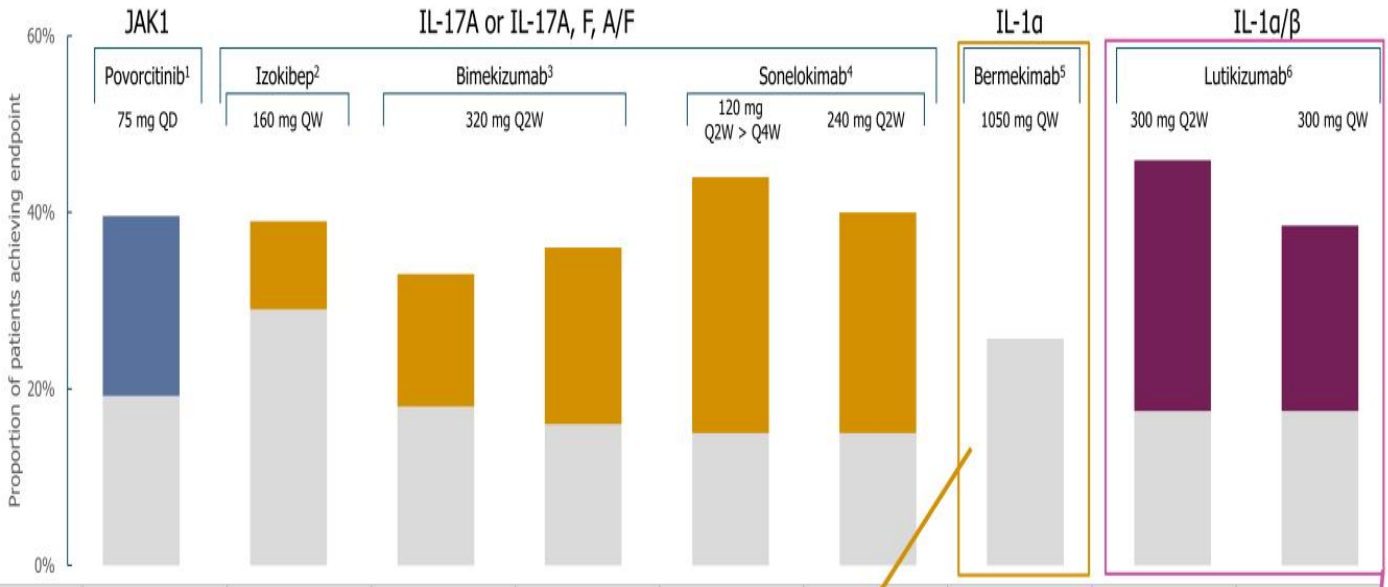
HS, hidradenitis suppurativa; IBD, inflammatory bowel disease; IL, interleukin; JAK1, janus kinase 1; MOA, mechanism of action; TNF, tumor necrosis factor.

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.

avalo THERAPEUTICS

# 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.



avalo THERAPEUTICS

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

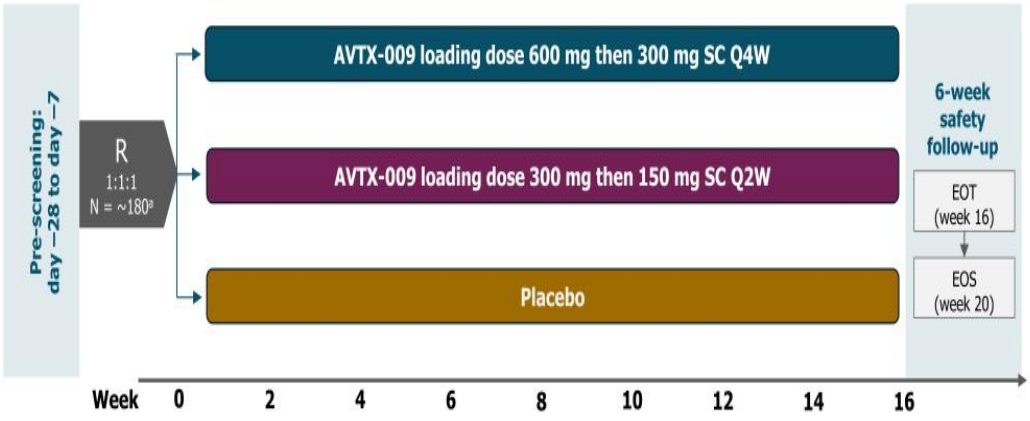
## Efficacy and Safety of AVTX-009 Treatment in Participants With Hidradenitis Suppurativa

### 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

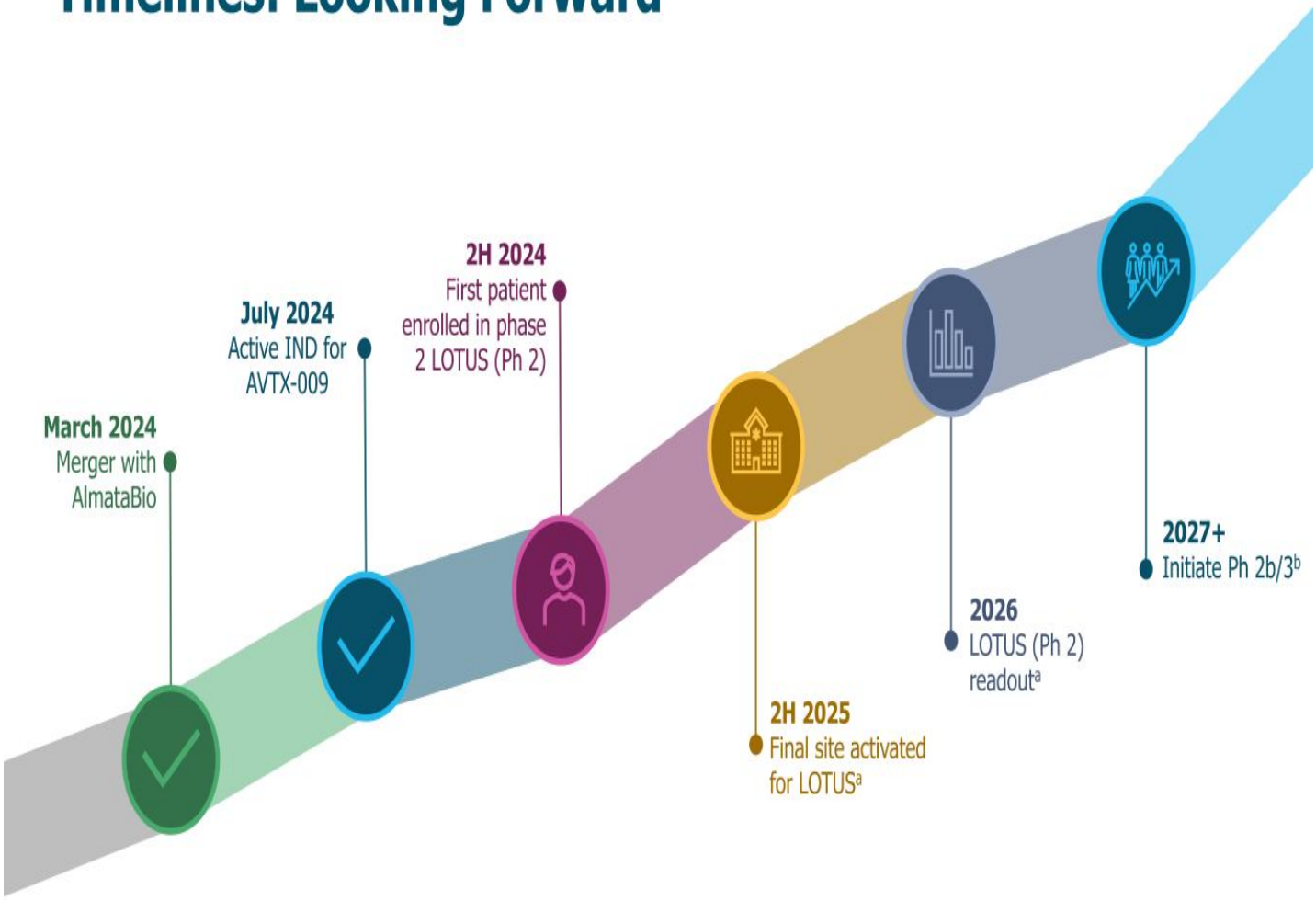
**Exploratory Endpoints**:
- PK
- HiSQOL, DLQI, PHQ-9
- Biomarkers:
  - CRP
  - IL-6
  - Potentially other biomarkers

[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.



avalo THERAPEUTICS

# Timelines: Looking Forward



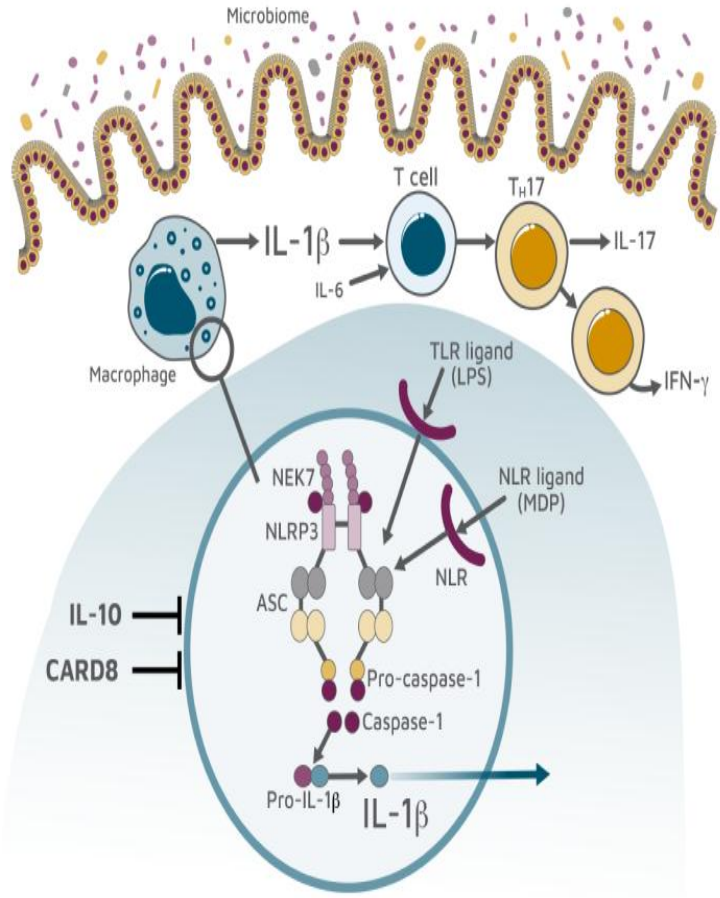

[a]Projected; [b]Pending readout from phase 2.
IND, investigational new drug application.

# Potential Additional Indications

avalo THERAPEUTICS

# 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

avalo
THERAPEUTICS

# 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 at least 2027**



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

# NASDAQ: AVTX

www.avalotx.com

avalo
THERAPEUTICS

# 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

avalo THERAPEUTICS