UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 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:

□ 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 \Box

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 January 13, 2025, 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.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVALO THERAPEUTICS, INC.

Date: January 13, 2025

By: /s/ Christopher Sullivan

Christopher Sullivan Chief Financial Officer

Avalo Therapeutics, Inc. (AVTX)

Corporate Presentation

January 2025



Exhibit 99.1

Forward-Looking Statements

This presentation may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forwardlooking 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 forwardlooking 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-1 β 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 preclinical 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 2035¹

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 200+ Years of Experience in Biotech/Pharma

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



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

- 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



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

 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;
 NCT04983732. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04983732; 5. NCT00942188. Clinicaltrials.gov. Accessed September 5, 2024. https://clinicaltrials.gov/study/NCT04983732; 5. NCT00942188. Clinicaltrials.gov/study/NCT00380744.

IL-1β is a Master Regulator of Inflammation

- IL-1β 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-1β 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, >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):5008; 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)



Chronic Inflammation in Hidradenitis Suppurativa Progresses to Tissue Destruction Areas commonly affected by

HS include⁴: Hidradenitis suppurativa is a chronic, often debilitating inflammatory skin disease that causes painful lumps, abscesses, and tunnels to form under the skin Nape of neck Tunnels Formed from progressing abscesses Infection and malodorous discharge Scarring Breast/chest Armpit Abscess Abdomen Follicular rupture Buttocks and anus Long-term inflammatory dysregulation Nodule Groin and genitals Continued extracellular matrix breakdown Formed from follicular blockage and remodeling Inner thighs Disease Progression 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. avalo 1. Diaz M), 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



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.

IL-1β 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-1β gene expression is up to 100x increased in HS lesions compared to skin in patients without HS1,2

IL-1 β is upstream of IL-17 and TNFa, both major effectors of inflammation³

Clinical benefit in HS has been observed with anti-IL-1 drugs4

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Phase 2 Lutikizumab Data Validates the Role for IL-1 in HS; Comparable Efficacy in a Refractory Population

HiSCR75



HISCR, hidradentitis 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. JAdD 2024;90(3):P521-529; 2. Acelvrin Press Release. September 11, 2023. Accessed September 10, 2024. https://investors.acelvrin.com/news-releases/news-release-details/acelvrin-inc-announces-top-lineresults-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-1ß Specificity, Higher Affinity, Bioavailability, and Longer Half-Life than Lutikizumab

	Lutikizumab ^{1,2}	AVTX-009 ³		
	IL-10		Poten Profile A	tial AVTX-009 dvantages in HS
Specificity	IL-1 (α&β)	IL-1β	Ø	Potential improved safety profile
IL-1 β Binding Affinity	44 K _D (pM)	<3 KD (pM)	V	Potential to
Subcutaneous bioavailability	46%	73%	V	translate to higher efficacy
Half-life	10-14 days	19 days	V	Potential for less
Dosing evaluated in HS study	Q1W & Q2W ⁴	Q2W & Q4W⁵	V	frequent dosing

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



 Suggests that anti-IL-1β agents may be more effective than anti-IL-1α in HS



 Bermekimab, an IL-1a 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

^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. 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.

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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 IL-1β IL-1β binding and inhibition Tissue infiltration

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 & Melbohm 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



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 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) ⁹	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 treatm CAGR, compound annual 1. HS Market Research 20 Dermatol Venerad, 2022	ent rates and biologic treatment rates are growth rate; HCP, healthcare provider; HS 024. Avalo Therapeutics Data on File; 2. G 36(0):1572-1605-5. Pinderknacht ER. Na	expected to increase over time. 5, hidradenitis suppurativa; US, United States. arg A, et al. <i>Am J Clin Dermatol.</i> 2023;24:977-990; W. HB. <i>Tri J Vionano, Dermatol.</i> 2024;10(1):e120.	3. Garg AX, et al. Dermatol Ther. 2022;3:581-594; 4. Ingram JR, et al. J Eur Acad

atol Venereol. 2022;36(9):1597-1605; 5. Rinderknecht FB, Naik HB. Int J Womens Dermatol. 2024;10(1):e130. Derm

Timelines: Looking Forward



Broad Potential for Indication Expansion



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

Arthritis Indications



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

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

Inflammatory Bowel 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 Additional Indications with Established Clinical Proof of Concept

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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www.avalotx.com



Appendix



Avalo Capitalization and Cash Position

As of December 31, 2024		Number of shares
Common Stock	Common shares outstanding ^{1,2}	10.5M
Assuming Conversion of Preferred Stock	Preferred stock ²	24.9M
Adjusted Share Count	• Adjusted common shares outstanding ^{1,2}	35.4M
Adjusted Market Capitalization	 Stock price Adjusted market capitalization 	\$7.43 \$262.8M

Cash of approximately \$134 million as of December 31, 2024², provides expected runway into at least 2027

¹Does not include 2.6M stock options and restricted stock units outstanding resulting in a fully dilutive share count of 38M, ²Cash, common shares outstanding and preferred shares outstanding as of December 31, 2024 are preliminary, unaudited and subject to change

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