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): July 9, 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 July 9, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing that the Investigational New Drug ("IND") for AVTX-009, an anti-IL-1β monoclonal antibody (mAb), for the treatment of hidradenitis suppurativa ("HS") is now active. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated July 9, 2024.
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: July 9, 2024

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

Avalo Therapeutics Announces Active IND for AVTX-009, an anti-IL-1β mAb, to Treat Hidradenitis Suppurativa

- Following FDA review, Avalo's IND application for AVTX-009 is active allowing Avalo to proceed with its Phase 2 trial (LOTUS) to evaluate the efficacy and safety of AVTX-009 in patients with hidradenitis suppurativa

WAYNE, PA and ROCKVILLE, MD, July 9, 2024 – Avalo Therapeutics, Inc. (Nasdaq: AVTX) today announced that the Investigational New Drug (IND) for AVTX-009, an anti-IL-1β monoclonal antibody (mAb), for the treatment of hidradenitis suppurativa (HS) is now active, permitting the Company to commence its Phase 2 (LOTUS) clinical trial in patients with HS. Avalo expects to enroll the first patient in its Phase 2 LOTUS Trial this year.

"This active IND is an important step for commencing the LOTUS trial in patients with hidradenitis suppurativa. I am proud of the Avalo team for achieving this milestone in just over three months from acquiring the product candidate in late March 2024," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"We believe that AVTX-009 has the potential to be best-in-class and best-in-indication because of its target, half-life, and potency, which may allow for strong efficacy and convenient dosing, and we look forward to getting the LOTUS Trial underway."*

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 HS. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Subjects will be randomized (1:1:1) to receive either one of two doses of AVTX-009 or placebo.

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 HS 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 product 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: timing of trial results and other risks, including reliance on investigators and enrollment of patients in clinical trials; integration of AVTX-009 into our operations; drug development costs; 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.

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

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