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 29, 2022

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 1.01 Entry Into a Material Definitive Agreement.

On July 29, 2022, Avalo Therapeutics, Inc. (the "Company") entered into a License Agreement (the "License Agreement") with Apollo AP43 Limited ("Apollo"), a wholly owned subsidiary of Apollo Therapeutics Group Limited, pursuant to which the Company (i) granted to Apollo a worldwide, exclusive license to the Company's intellectual property rights concerning its anti-IL18 monoclonal antibody product ("AVTX-007") and (ii) entered into a Novation Agreement, dated July 29, 2022, pursuant to which the Option and License Agreement, dated August 6, 2019, between the Company and MedImmune, will be replaced by a substantially similar novated license agreement between Apollo and MedImmune Limited ("MedImmune"; such Option and License Agreement, the "MedImmune License"). Pursuant to the License Agreement, the Company also is required to transfer to Apollo certain specified third-party contracts related to the development or manufacture of AVTX-007. The Company was pursuing AVTX-007 as a treatment for Still's disease. The Company originally acquired rights to AVTX-007 under the MedImmune License when the Company completed its merger with Aevi Genomic Medicine, Inc. in February 2020.

Within five (5) business days of execution of the License Agreement, Apollo will pay the Company $5 million as an upfront fee and an additional approximate $10 million as partial consideration for transition, consulting and transfer activities. Apollo will pay the Company up to $6.25 million in regulatory or development milestones and up to $67.5 million in milestones based on annual global net sales of any product licensed under the License Agreement. Apollo also will pay the Company a royalty payment of a low single digit percentage of annual net sales, which percentage increases to another low single digit percentage if annual net sales exceed a specified amount. The royalty term for any licensed product, on a country-by-country and product-by-product basis, begins upon the first commercial sale of a product in a country and extends until the later of (X) the latest of (a) 10 years from the first commercial sale of the first licensed product sold in such country, (b) the first date upon which there are no issued valid claims including in the licensed patent rights covering such product in such country, or (c) the expiration of regulatory exclusivity for such product in such country or (Y) the expiration of the applicable royalty term for such product and country as defined in the MedImmune License.

The License Agreement will end upon the last to expire royalty term. The License Agreement is terminable: by either party for uncured material breach by the other party (provided such right of the Company applies to the License Agreement in its entirety, but such right of Apollo applies on country-by-country or product-by-product basis or to the entire License Agreement); by the Company, in its entirety, if Apollo abandons its efforts with respect to developing or commercializing licensed products and provides notice thereof to Avalo; by the Company if the novated MedImmune License agreement is terminated with respect to one or more products (terminable for any such product), one or more countries (terminable for any such country) or in its entirety (provided that such Company right shall only apply to the extent the MedImmune License is so terminated); and by Apollo in its discretion upon 90 days' notice in the event that regulatory approval has not been obtained for a product or upon 180 days' notice in the event that regulatory approval has been obtained for a product, upon a product-by-product or country-by-country basis. The License Agreement also contains terms for the transfer of certain material to Apollo, transition services to assist with the transfer of AVTX-007 to Apollo, and customary representations, warranties and covenants of the Company and Apollo, including indemnification.

Pursuant to the terms of the License Agreement, the parties have agreed to transition to Apollo responsibility for conducting the currently ongoing study for AVTX-007 for the treatment of adult-onset Still's disease, with the Company remaining responsible for continuing such study, at Apollo's expense, until such transition.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2022 (the "Form 10-Q"). The Company intends to seek confidential treatment for certain terms of the License Agreement at the time of filing such agreement with the Form 10-Q, which will be redacted from the exhibit.

Item 8.01 Other Events.

On August 1, 2022, the Company issued a press release to report its entry into the License Agreement. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release, dated August 1, 2022.
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: August 1, 2022

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

Avalo Therapeutics Transfers Anti-IL-18 Antibody, AVTX-007 (camoteskimab) to Apollo Therapeutics

- Avalo to receive an approximately $15 million upfront payment, up to $74 million in milestone payments
- Apollo to lead continued clinical development of AVTX-007, currently in Phase 1b

ROCKVILLE, MD, and CAMBRIDGE, United Kingdom, August 01, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX) and Apollo Therapeutics Group Limited have entered into a worldwide, exclusive license agreement granting rights to Apollo to research, develop, manufacture and commercialize AVTX-007 (camoteskimab), Avalo's anti-IL-18 monoclonal antibody product. Under the terms of the agreement, Apollo will assume responsibility for the future development of AVTX-007, including the ongoing clinical trial. Apollo will lead future clinical development in its selected therapeutic indications.

"This transaction is critically important to Avalo. It extends our cash runway and allows us to increase our focus on our lead molecule, AVTX-002, and our ongoing phase 2 PEAK trial evaluating AVTX-002 for the treatment of non-eosinophilic asthma," said Garry A. Neil, MD, President and Chief Executive Officer of Avalo Therapeutics.*"Furthermore, we are excited to transition camoteskimab to a capable and well-funded partner in Apollo Therapeutics whom we expect will progress the development of this promising asset to the potential benefit of patients and our collective financial interests."*

"We are pleased to have entered into this agreement with Avalo and look forward to building upon the work done to date with camoteskimab," said Richard Mason, MD, chief executive of Apollo. "With our university partners we have built translational leadership in three core areas of biological focus – immunology, cell signaling, and cell stress responses and metabolism – and the addition of this Phase 2 ready antibody for an important inflammasome target substantially accelerates the growth of our pipeline in this area of immunology, where we are advancing additional preclinical programs. We seek further opportunities to acquire clinical assets in our areas of biological and therapeutic focus."

Pursuant to the license agreement, Avalo will receive within 5 days of execution of the agreement $5 million of upfront fee and an additional approximately $10 million as consideration for transfer activities. Apollo will also pay Avalo up to $74 million of milestones, as well as a royalty payment of a low single digit percentage of annual net sales.

The AVTX-007 program was originally licensed to Avalo by MedImmune Limited, a subsidiary of AstraZeneca plc, and such license was transferred to Apollo as part of the transaction.

About AVTX-007 (camoteskimab)
Camoteskimab is a high affinity, fully human monoclonal antibody targeting the proinflammatory cytokine IL-18.

About Avalo Therapeutics
Avalo Therapeutics is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. The Company's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

For more information about Avalo, please visitwww.avalotx.com.

About Apollo Therapeutics Group Limited
Apollo Therapeutics is a biopharmaceutical company, rapidly advancing a robust pipeline of potentially transformative therapeutic programs based on breakthrough discoveries. We identify and develop pre-clinical and clinical stage assets with strong biological hypotheses and the potential to become meaningful new treatment options. Our team combines 'drug hunters' and deep subject matter experts who together are building an expansive and de-risked portfolio in oncology, major inflammatory disorders, and rare diseases. Backed by leading specialist investors including Patient Square Capital and Rock Springs Capital, we have operations in Cambridge, UK, and Boston, USA. Apollo Therapeutics has core innovation sourcing and drug discovery collaborations with four of the world's leading universities; University of Cambridge, University College London, Imperial College London, and Kings College London.

For more information, please visit apollotherapeutics.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: the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the future financial and operational outlook; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: Avalo's cash position and the potential need for it to raise additional capital; risks relating to the effect of the reverse stock split on the Company's stock price; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel, including as a result of recent management changes; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and tensions in Ukraine; and those other risks detailed in Avalo's filings with the SEC. 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.

For media and investor inquiries

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

or

Chris Brinzey
ICR Westwicke
Chris.brinzey@westwicke.com
339-970-2843

For Apollo Therapeutics

US Media Contact
Kate Burdick
Canale Communications
Kate.Burdick@canalecomm.com
860 462 1569

UK/Europe Media Contact
Melanie Toyne-Sewell / Rozi Morris / Agnes Stephens
Instinctif Partners
apollotx@instinctif.com
+44 207 457 2020