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): August 19, 2024

Apogee Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-41740**	**93-4958665**
(State of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

221 Crescent Street, Building 17, Suite 102b,
Waltham, MA, 02453
(Address of Principal Executive Offices, including Zip Code)

(650) 394-5230
(Registrant's telephone number, including area code)

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, par value $0.00001 per share	**APGE**	**The Nasdaq Global 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 7.01 Regulation FD Disclosure.

On August 19, 2024, Apogee Therapeutics, Inc. (the "Company" or "Apogee") issued a press release announcing that it has initiated dosing of healthy volunteers in its first clinical trial for APG990, a novel, subcutaneous half-life extended monoclonal antibody targeting OX40L, which is initially being developed as a treatment for people living with atopic dermatitis ("AD"). A copy of the press release is furnished herewith as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On August 19, 2024, the Company announced that it has initiated dosing of healthy volunteers in its first clinical trial for APG990, a novel, subcutaneous half-life extended monoclonal antibody targeting OX40L, which is initially being developed as a treatment for people living with atopic dermatitis. The APG990 Phase 1 clinical trial is designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose trial in healthy volunteers. The study will evaluate the safety, tolerability and pharmacokinetics of APG990 and is expected to enroll approximately 40 healthy adults into five cohorts. Apogee expects interim data from the trial in 2025. Based on its preclinical studies, the Company believes APG990 can be dosed every three to six months in maintenance, which, if the Company's clinical trials are successful, would represent a significant improvement compared to first generation OX40L antibodies that are expected to be dosed every four to twelve weeks.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, statements regarding: Apogee's plans for its current and future clinical trials, including its Phase 1 clinical trial for APG990; Apogee's plans for clinical trial design; the anticipated timing of the initiation of and results from Apogee's clinical trials, including data from Apogee's Phase 1 clinical trial of APG990; and the potential clinical benefit and half-life of APG990 and any other potential programs, including combination therapies. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Apogee believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Apogee's filings with the U.S. Securities and Exchange Commission (the "SEC")), many of which are beyond the company's control and subject to change. Actual results could be materially different. Risks and uncertainties include: global macroeconomic conditions and related volatility, expectations regarding the initiation, progress, and expected results of Apogee's preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of Apogee's clinical trials; the unpredictable relationship between preclinical study results and clinical study results; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in Apogee's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 5, 2024, Quarterly Report on 10-Q for the quarterly period ended June 30, 2024, filed with the SEC on August 12, 2024, and subsequent disclosure documents it may file with the SEC. The Company claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibit is being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 19, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Apogee Therapeutics, Inc.

Date: August 19, 2024

By: /s/ Michael Henderson, M.D.
Name: Michael Henderson, M.D.
Title: Chief Executive Officer

Exhibit 99.1

Apogee Therapeutics Announces First Participants Dosed in Phase 1 Clinical Trial of APG990, its Novel Half-Life Extended OX40L Antibody for the Treatment of Atopic Dermatitis and Other Inflammatory Diseases

Interim safety and pharmacokinetic data from Phase 1 healthy volunteers trial anticipated in 2025

Initiation of the first clinical trial of APG777 and APG990 combination expected to commence in 2025 with the potential for greater efficacy in atopic dermatitis and across I&I diseases

San Francisco, CA and Waltham, MA, August 19, 2024 – Apogee Therapeutics, Inc., (Nasdaq: APGE), a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other I&I indications, today announced that it has initiated dosing of healthy volunteers in its first clinical trial for APG990, a novel, subcutaneous (SQ) half-life extended monoclonal antibody targeting OX40L, which is being developed initially as a treatment for people living with AD.

"The early initiation of the APG990 Phase 1 clinical trial marks another significant milestone for Apogee as we continue to focus on excellence in execution. We have advanced three of our programs into clinical trials in just 12 months, bringing potentially differentiated treatments closer to patients living with the largest I&I diseases," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "We are initially exploring APG990 for AD, and we believe combining two of the most active, orthogonal mechanisms of IL-13 (APG777) with OX40L (APG990) has the potential to expand patient reach with best-in-class efficacy and dosing. This approach underscores our relentless pursuit for the next wave of innovation in treating patients with AD. We refuse to stop at 'good enough.'"

The APG990 Phase 1 clinical trial is designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose trial in healthy volunteers. The study will evaluate the safety, tolerability and pharmacokinetics (PK) of APG990 and is expected to enroll approximately 40 healthy adults into 5 cohorts. Apogee expects interim data from the trial in 2025. Pending positive results from the Phase 1 clinical trial and following submission of an Investigational New Drug application or foreign equivalent, the company plans to initiate a Phase 1 clinical trial of APG777 and APG990 as a potential first-in-class approach to test the combination of deep and sustained inhibition of Type 2 inflammation via APG777's targeted inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. The company plans to initiate the first clinical trial of the APG777 and APG990 combination in 2025.

"The progression of the APG990 program represents an important advancement in our efforts to enhance treatment options for patients with AD," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "AD is a heterogeneous disease where Type 2 inflammation is the core pathway with varying involvement of Type 1 and Type 3 inflammation. While currently available treatments are targeted at the Type 2 pathway, OX40L has been clinically validated to provide broad inhibition of all three inflammation pathways and could enhance treatment options for patients. We plan to investigate APG777 and APG990, our extended half-life mAbs, which could provide both deeper and broader responses, delivering the potential for better overall outcomes and best-in-class dosing for patients living with AD and other I&I diseases."

About APG990

APG990 is a novel, SQ half-life extended mAb targeting OX40L, initially being developed for AD. OX40L is located further upstream in the inflammatory pathway than IL-13 or IL-4Rα and targeting it could potentially have broader impact on the inflammatory cascade by inhibiting Type 1, Type 2 and Type 3 pathways. AD is a heterogeneous disease and varies by age, severity and ethnicity. With current approved biologics only targeting two mechanisms of action (IL-13 and IL4Rα) in AD, OX40L could represent another therapeutic option for patients, especially the portion of patients who do not benefit from currently available treatments. In our head-to-head preclinical assays, APG990 has demonstrated similar or improved potency to amlitelimab. In our head-to-head studies of APG990 and amlitelimab in non-human primates, APG990 demonstrated a half-life of 26 days versus 21 days for amlitelimab. In addition, based on our preclinical studies, we believe APG990 can be dosed every three to six months in maintenance, which, if our clinical trials are successful, would represent a significant improvement compared to first generation OX40L antibodies that are expected to be dosed every four to twelve weeks.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other I&I indications. Apogee's antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties. APG777, the company's most advanced program, is being initially developed for the treatment of AD, which is the largest and one of the least penetrated I&I markets. With four validated targets in its portfolio, Apogee is seeking to achieve best in class efficacy and dosing through monotherapies and combinations of its novel antibodies. Based on a broad pipeline and depth of expertise, the company believes it can deliver value and meaningful benefit to patients underserved by today's standard of care. For more information, please visit www.apogeetherapeutics.com.

Forward Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, statements regarding: Apogee's plans for its current and future product candidates and programs, its plans for current and future clinical trials, including a Phase 1 clinical trial for APG990 and a Phase 1 clinical trial for APG990 in combination with APG777; Apogee's plans for clinical trial design; the anticipated timing of the initiation of and results from Apogee's clinical trials, including data from Apogee's Phase 1 clinical trial of APG990; and the potential clinical benefit and half-life of APG777, APG990 and any other potential programs, including combination therapies. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Apogee believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Apogee's filings with the U.S. Securities and Exchange Commission (the SEC)), many of which are beyond the company's control and subject to change. Actual results could be materially different. Risks and uncertainties include: global macroeconomic conditions and related volatility, expectations regarding the initiation, progress, and expected results of Apogee's preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of Apogee's clinical trials; the unpredictable relationship between preclinical study results and clinical study results; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in Apogee's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 5, 2024, Quarterly Report on 10-Q for the quarterly period ended June 30, 2024, filed with the SEC on August 12, 2024, and subsequent disclosure documents we may file with the SEC. Apogee claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Apogee expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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