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): December 2, 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 December 2, 2024, Apogee Therapeutics, Inc. (the Company or Apogee) issued a press release titled "Apogee Therapeutics Highlights Progress and Best in Class Potential of Novel Biologic Programs for I&I Diseases at 2024 Inaugural R&D Day." The Company will host its Virtual R&D Day via webcast today, Monday, December 2, 2024, at 10:00 am, Eastern Time.

The Company will be posting to its website the presentation to be used in the Company's Virtual R&D Day. The presentation and replays of the webcast will be available on the Company's website at https://apogeetherapeutics.com.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On December 2, 2024, the Company will host a Virtual R&D Day and provide an update on its APG808 Phase 1 trial, share additional data up to 12 months from the APG777 Phase 1 trial, share details around the Company's strategy for combinations in atopic dermatitis (AD), asthma and chronic obstructive pulmonary disease (COPD) to deliver better efficacy and dosing regimens, and share the expected significant commercial potential of its programs. The updates to be provided include:

APG808 interim Phase 1 healthy volunteer trial results

The APG808 Phase 1 trial enrolled 32 healthy adult participants into four single-ascending dose (SAD) cohorts. The Company shared interim data from all four SAD cohorts with at least 3-months follow-up:

- APG808 demonstrated a potential best-in-class PK profile, including a half-life of approximately 55 days, supporting the potential for every 2- to 3- month maintenance dosing.
- Single doses of APG808 demonstrated a deep and sustained effect on pharmacodynamic (PD) markers out to ~3 months (longest follow-up available at time of data cut).
- APG808 was well tolerated across all dose groups.
- The Company is also now evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

Accelerating a leading franchise in AD

The Company is advancing multiple opportunities for best-in-class monotherapy and first-in-class combination approaches for the treatment of AD that could provide transformational dosing and efficacy compared to current approved and investigational biologics.

APG777

APG777 is a novel, subcutaneous (SQ) extended half-life monoclonal antibody (mAb) targeting IL-13 with the potential for best-in-class efficacy and dosing compared to currently approved biologics. APG777 is being evaluated in an ongoing Phase 1 trial, which initiated in August 2023, and a global Phase 2 trial in AD, which initiated in May 2024.

- The Company provided updated data from its Phase 1 trial, which is now out to 12 months, including a half-life of 77 days, consistent safety with prior data and favorable PD profile showing near complete inhibition of pSTAT6 for up to 12 months after a single administration and sustained TARC inhibition.
    - These latest data support the potential path for APG777 to be dosed annually, which could create yet another opportunity to disrupt the future $50B+ AD market that is currently served by therapies that require dosing every 2-4 weeks.

- The Phase 1 data continue to support the Company's ongoing Phase 2 trial of APG777 in patients with AD, demonstrating potential for improved clinical responses from greater exposures in induction and maintenance dosing of every 3- or 6-months.
    - Based on strong enrollment in the Phase 2 trial to date, the Company now expects to report 16-week topline data from Part A of the APG777 Phase 2 trial in mid-2025. The observed strong correlation between Phase 2 and Phase 3 data makes the 16-week induction data a key catalyst.
    - The Company plans to advance the development of APG777 in asthma and eosinophilic esophagitis (EoE), by initiating a Phase 1b trial in asthma in the first half of 2025, followed by a Phase 2b trial in asthma in the second half of 2025, and launching a Phase 2 trial in EoE in 2026.

Raising the bar in AD and beyond via broader inhibition

The Company plans to take a first-in-class combination approach to AD by targeting Types 1-3 inflammation, potentially offering JAK-like inhibition without associated safety concerns. This approach offers the potential for improved clinical responses over monotherapies and best-in-class dosing.

APG777 + 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 and targeting it could have broader impact on the inflammatory cascade by inhibiting Type 1, Type 2 and Type 3 pathways. The Company is evaluating APG990 in a Phase 1 healthy volunteer trial to establish safety, tolerability and PK profile, which could enable combination with APG777.

- The APG777 + APG990 coformulation has been shown to retain stability, injectability, and convenience of individual components. In preclinical studies it has demonstrated broad inhibition of Type 1, Type 2 and Type 3 inflammation with potential for better tolerability than JAK inhibitors.
- Pending APG990's Phase 1 results expected in the first half of 2025, the Company plans to initiate its first combination trial in 2025 – a Phase 1b trial designed to evaluate the safety, PK, PD and efficacy of the combination of APG777 and APG990 against DUPIXENT in ~50-75 patients with moderate-to-severe AD with readout expected in the second half of 2026.

Breaking through the efficacy ceiling in asthma and COPD

The Company plans to take a combination approach to the treatment of asthma and COPD, leveraging mechanisms that address both central and local drivers of respiratory diseases, potentially enabling enhanced efficacy and extended dosing regimens.

APG777 + APG333

APG333 is a novel, SQ extended half-life mAb targeting thymic stromal lymphopoietin (TSLP), a key driver of Type 2 and Type 3 inflammation in eosinophilic and non-eosinophilic conditions. A Phase 1 trial in healthy volunteers is planned to commence by the end of 2024, with data expected in the second half of 2025.

- In preclinical studies, the combination of APG777 + APG333 has been shown to drive broader and deeper inhibition of inflammation centrally with deeper impact on local airway responses compared to approved or in-development biologics, with the potential for a significantly less frequent dosing schedule.
- The Company plans to evaluate APG777 and APG333 monotherapies in respective Phase 1b trials in patients with asthma in 2025 to support advancement into future combination trials in asthma and COPD.

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 product candidates and programs, particularly APG777, APG990 and APG333; its plans for current and future clinical trials; expected timing for release of data from Apogee's APG808 Phase 1b trial, Part A of the APG777 Phase 2 trial and APG333 Phase 1 trial; the potential clinical benefit, dosing schedule and half-life of APG777 and APG808; plans for and potential benefit of Apogee's other product candidates, 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 September 30, 2024, filed with the SEC on November 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.

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 December 2, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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: December 2, 2024

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

Exhibit 99.1

Apogee Therapeutics Highlights Progress and Best-in-Class Potential of Novel Biologic Programs for I&I Diseases at 2024 Inaugural R&D Day

Positive interim Phase 1 data indicate APG808 was well-tolerated with half-life of approximately 55 days, supporting potential for 2- to 3- month dosing and demonstrating deep and sustained inhibition of biomarkers

Data up to 12 months reinforce APG777's best-in-class potential, including 77-day half-life, and provide a potential path to annual dosing

16-week topline data from APG777 Phase 2 Part A trial in AD accelerated to mid-2025 based on strong enrollment

Preclinical and coformulation proof-of-concept achieved for APG777 + APG990 combination Phase 1b head-to-head trial against DUPIXENT expected to initiate in 2025 with data in 2H 2026

Preclinical proof-of-concept achieved for APG777 + APG333 combination in asthma and COPD, clinical trial planning underway

Webcast to be held today at 10:00 a.m. ET

SAN FRANCISCO and WALTHAM, Mass., December 2, 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), eosinophilic esophagitis (EoE) and other I&I indications, will highlight updates from across its pipeline during today's Virtual R&D Day, being held at 10:00 a.m. ET. Updates include positive interim results from the APG808 Phase 1 trial, data up to 12 months from the APG777 Phase 1 trial, details around the Company's strategy for combinations in AD, asthma and COPD to deliver better efficacy and dosing regimens, and the expected significant commercial potential of its programs. Key opinion leaders, Emma Guttman-Yassky, M.D., Ph.D. and David Singh, M.D., FERS, FBPhS, will also discuss the current landscape and need for new treatment opportunities for patients living with I&I conditions.

"APG777 is poised to disrupt the atopic dermatitis market, with our most recent data suggesting potential dosing as infrequently as once per year -- a revolutionary advancement that has garnered positive feedback from patients, physicians and payers alike," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "We plan on transforming the standard of care in I&I through three waves of innovation: progressing APG777's monotherapy program with potential for higher efficacy and transformational dosing in AD, currently in a Phase 2 Part A 16-week trial, with its proof of concept (PoC) readout that has been accelerated to mid-2025 based on strong enrollment; demonstrating APG777's pipeline-in-a-product monotherapy potential by expanding into EoE as well as asthma; and advancing the first AD combination PoC trial next year with respiratory combo planning underway. Beyond its differentiation as a monotherapy, APG777 combined with APG990 as well as with APG333 presents the opportunity for enhanced efficacy and best-in-class dosing for patients."

“We’re pleased to report positive safety, PK and PD data from the Phase 1 healthy volunteer trial of APG808 at today’s R&D Day,” said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. “Our interim findings demonstrated an approximately 55-day half-life for APG808, a five-fold increase versus DUPIXENT, suggesting a potential dosing regimen of every 2- to 3-months, compared to every 1-2 weeks for DUPIXENT. We believe the results support Apogee’s ability to engineer optimized antibodies and target known biologic drivers to improve the lives of patients with I&I conditions. We look forward to further evaluating APG808 in the Phase 1b trial in asthma as well as delivering data on additional pipeline candidates next year.”

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- Apogee plans to evaluate APG777 and APG333 monotherapies in respective Phase 1b trials in patients with asthma in 2025 to support advancement into future combination trials in asthma and COPD.

Event Information

Apogee Therapeutic's Virtual R&D Day will begin at 10:00 a.m. ET. The live webcast can be accessed via this link or News & Events page in the Investors section of the Apogee Therapeutics website. A replay of the webcast will be archived on the website following the event. It is recommended that participants register at least 15 minutes in advance of the event.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest I&I markets, including for the treatment of AD, asthma, COPD, EoE 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 https://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, particularly APG777, APG990 and APG333; its plans for current and future clinical trials; expected timing for release of data from Apogee's APG808 Phase 1b trial, Part A of the APG777 Phase 2 trial and APG333 Phase 1 trial; the potential clinical benefit, dosing schedule and half-life of APG777 and APG808; plans for and potential benefit of Apogee's other product candidates, 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 September 30, 2024, filed with the SEC on November 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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