# 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): February 3, 2025**

# 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 February 3, 2025, Apogee Therapeutics, Inc. (the "Company" or "Apogee") issued a press release announcing that the first patient has been dosed in the Part B portion of the Phase 2 APEX clinical trial of APG777 in patients with moderate-to-severe atopic dermatitis ("AD"), and that enrollment has been completed in the Part A portion of the trial. 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 February 3, 2025, the Company announced that the first patient has been dosed in the Part B portion of the Phase 2 APEX clinical trial of APG777 in patients with moderate-to-severe AD, and that enrollment has been completed in the Part A portion of the trial.

APEX is a Phase 2 randomized, placebo-controlled clinical trial evaluating APG777, a novel, subcutaneous extended half-life monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD, in patients with moderate-to-severe AD. The trial was designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. Part A exceeded expected enrollment with 123 patients randomized 2:1 to APG777 versus placebo. Part B is a placebo-controlled dose optimization with approximately 280 patients randomized 1:1:1:1 to high, medium, or low dose APG777 versus placebo. The primary endpoint of each part of the study is mean percentage change in Eczema Area and Severity Index ("EASI") score from baseline at week 16 and secondary endpoints include EASI-75 and Investigator's Global Assessment 0/1 at week 16. Patients benefiting from treatment will continue to APG777 maintenance dosing, which will evaluate 3- or 6-month dosing. Apogee expects Part A 16-week induction data in mid-2025, maintenance data in the first half of 2026 and Part B 16-week data in the second half of 2026.

**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 2 APEX clinical trial of APG777; Apogee's plans for clinical trial design; the anticipated timing of the results from Apogee's clinical trials, including data from Apogee's Phase 2 APEX clinical trial of APG777; and the potential clinical benefit and half-life of APG777 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 Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 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 February 3, 2025 |
| 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: February 3, 2025

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

Exhibit 99.1

**Apogee Therapeutics Announces First Patient Dosed in Part B of Phase 2 APEX Trial of APG777 in Patients with Moderate-to-Severe Atopic Dermatitis**

*Enrollment of Part A completed ahead of schedule and exceeded enrollment target with 123 patients enrolled*

*Part A 16-week proof-of-concept data anticipated in mid-2025*

**SAN FRANCISCO and BOSTON, February 3, 2025 --** 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, today announced the first patient has been dosed in the Part B portion of the Phase 2 APEX clinical trial of APG777 in patients with moderate-to-severe AD, as well as enrollment completion in the Part A portion of the trial.

"Enrollment for the Phase 2 Part A trial of APG777 surpassed the approximately 110 patient target ahead of schedule, driven by strong patient and investigator enthusiasm, underscoring the potential of APG777 to address the need for safe, effective treatment options that reduce injection burden and provide better disease control for patients with AD and other I&I conditions," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "Positive results from our Phase 1 healthy volunteer trial enabled us to design this Phase 2 trial whereby APG777 is modeled to exceed lebrikizumab exposures by ~30-40% with potential for improved clinical responses, as well as approximately half the number of injections during induction and ~70-90% fewer injections in maintenance compared to currently available therapies. Our uniquely designed Phase 2 trial allowed us to seamlessly transition from completing enrollment in Part A to enrolling Part B within one week, streamlining the clinical development process and potentially enabling us to bring APG777 to patients sooner."

APEX is a Phase 2 randomized, placebo-controlled clinical trial evaluating APG777, a novel, subcutaneous (SQ) extended half-life monoclonal antibody (mAb) targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD, in patients with moderate-to-severe AD. The trial was designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. Part A exceeded expected enrollment with 123 patients randomized 2:1 to APG777 versus placebo; patients assigned to APG777 received induction regimen dosing of 720mg at weeks 0 and 2, followed by 360mg at weeks 4 and 12 and the trial has greater than 90% power for the primary endpoint. Patients benefiting from treatment will continue to APG777 maintenance dosing, which will evaluate 3- or 6-month dosing. Part B is a placebo-controlled dose optimization with approximately 280 patients randomized 1:1:1:1 to high, medium, or low dose APG777 versus placebo and the first patient in Part B have now been dosed. The primary endpoint of each part of the study is mean percentage change in EASI score from baseline at week 16. Secondary endpoints include EASI-75 and IGA 0/1 at week 16.

APG777 is currently in clinical development as a monotherapy for AD with several proof-of-concept anticipated readouts in 2025 and 2026, including Part A 16-week induction data in mid-2025 and maintenance data in the first half of 2026 as well as Part B 16-week data in the second half of 2026. Apogee plans to advance development of APG777 in expansion indications 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. In addition, Apogee plans to evaluate APG777 in combination with other investigational therapies within Apogee's pipeline to potentially enable greater efficacy and improved safety for I&I conditions. Apogee plans to initiate its first combination study, a Phase 1b trial of APG777 and APG990, a novel, SQ, half-life extended mAb targeting OX40L, in 2025. This combination study is designed to evaluate the safety, PK, PD and efficacy against DUPIXENT in patients with moderate-to-severe AD, with readout expected in the second half of 2026.

**About APG777**

APG777 is a novel, subcutaneous half-life extended monoclonal antibody targeting IL-13 for the potential treatment of AD. In head-to-head preclinical studies, APG777 showed equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling. APG777 Phase 1 trial data out to 12 months demonstrated a half-life of 77 days, a consistent safety and favorable PD profile showing near complete inhibition of pSTAT6 for up to 12 months after a single administration and sustained TARC inhibition. AD is a chronic inflammatory skin disorder with an estimated population of 82 million people worldwide afflicted with moderate-to-severe AD. Based on initial clinical data, the company plans to initiate a Phase 1b and 2b trial in asthma, a Phase 2 trial in EoE and plans to further evaluate opportunities to develop APG777 for other I&I indications, including alopecia areata, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria, and prurigo nodularis.

**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; its plans for current and future clinical trials, including trial design and expected timing; expected timing for release of the initial Part A data from Apogee's Phase 2 clinical trial of APG777 in AD; the potential clinical benefit, dosing schedule and half-life of APG777; plans for 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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