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): March 5, 2024

Apogee Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-41740**	**88-0588063**
(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 2.02 Results of Operations and Financial Condition.

On March 5, 2024, Apogee Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2023.

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 2.02 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 (the "Securities Act"), regardless of any general incorporation language in such filing.

Item 7.01 Regulation FD Disclosure.

On March 5, 2024, the Company issued a press release announcing positive initial Phase 1 data from its first-in-human study of APG777, one of its lead product candidates being developed as a frontline treatment for moderate-to-severe atopic dermatitis and other inflammatory diseases. The Company will host a conference call and webcast today, Tuesday, March 5, 2024, at 7:00 am, Eastern Time, to discuss the data results.

A copy of the press release is furnished as Exhibit 99.2 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 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, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Earnings Press Release, dated March 5, 2024
99.2	Data Press Release, dated March 5, 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: March 5, 2024

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

Exhibit 99.1

Apogee Therapeutics Provides Pipeline Progress and Reports Fourth Quarter and Full Year 2023 Financial Results

Positive interim results from APG777 Phase 1 healthy volunteer clinical trial exceeded objectives with approximately 75-day half-life which supports the potential for higher exposures leading to potential for improved clinical responses in induction than currently available biologic therapies and the potential for maintenance dosing of every 3- or 6-months

APG777 Phase 1 interim data support advancement of a randomized, placebo-controlled Phase 2 clinical trial in patients with moderate-to-severe atopic dermatitis in 1H 2024 ahead of schedule

Phase 1 healthy volunteer clinical trial set to start ahead of schedule for APG808, a subcutaneous extended half-life antibody targeting IL-4Rα, following receipt of regulatory clearance in February

Total cash of $395.5 million at year end 2023 with expected cash runway into 4Q 2026

San Francisco, CA and Waltham, MA, March 5, 2024 – Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology (I&I) indications, today reported pipeline highlights and fourth quarter and full year 2023 financial results.

"2023 was a momentous year for Apogee with the completion of a successful IPO, initiation of our first clinical program of APG777 in healthy volunteers and the nomination of our second pipeline candidate, APG808," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "Our momentum and track record of execution have continued in 2024, and we were thrilled to disclose positive interim results from our Phase 1 trial of APG777 today, which demonstrated a favorable safety profile and exceeded our trial objectives on both pharmacokinetics and pharmacodynamics. This data readout is a key risk-reducing milestone for our APG777 program and pipeline and supports a path forward into a Phase 2 trial for APG777 in patients with AD in the first half of this year. Looking ahead to the rest of the year, we continue to make progress with APG808, for which we are set to start a Phase 1 healthy volunteer clinical trial ahead of schedule while advancing our earlier programs, APG990 and APG222. With each of our programs, we have the potential to reshape the standard of care with potential best-in-class or first-in-class therapeutic candidates for I&I diseases."

Pipeline Highlights and Upcoming Milestones

- **Positive, interim Phase 1 results for APG777 exceeded trial objectives and delivered ahead of schedule**: APG777 is a novel, subcutaneous (SQ) extended half-life monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD. Today, the company reported positive interim results in the Phase 1 first-in-human study of APG777, designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single-ascending and multiple-ascending doses of APG777 in healthy volunteers. Key findings from the study include:
    - Potentially best-in-class PK profile, including a half-life of approximately 75 days, supporting:

- Testing higher exposures of drug in induction to potentially achieve improved clinical responses
- Testing of maintenance dosing of every 3- or 6-months, representing 2-4 injections per year compared to the current treatment paradigm of 13-26 injections per year

  - Single doses of APG777 showed deep and sustained effect on key AD biomarkers pSTAT6 and TARC for approximately 3 months (longest follow-up available with inhibition still ongoing at the time of the data cut
  - APG777 was well tolerated across all dose groups with a favorable safety profile consistent with the anti-IL-13 class
  - Based on these data, Apogee plans to initiate a randomized, placebo-controlled Phase 2 clinical trial in patients with moderate-to-severe AD in the first half of 2024; modeled induction and maintenance dosing for the Phase 2 trial suggests APG777 could reach exposures approximately 30-40% greater than lebrikizumab in induction and potentially enable every 3- or 6- month maintenance dosing
  - 16-week proof-of-concept data from this Phase 2 trial is expected in second half of 2025
  - Apogee also plans to evaluate APG777 in expansion indications including initiating a Phase 2 trial in asthma in 2025

- **Phase 1 APG808 healthy volunteer clinical trial set to start ahead of schedule:** Apogee's second program, APG808, is novel, SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding and femtomolar affinity for IL-4Rα as compared to a first generation mAb, DUPIXENT, and has demonstrated similar inhibition to DUPIXENT across three in vitro assays which measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion). An APG808 Phase 1 healthy volunteer clinical trial is expected to start ahead of schedule following receipt of regulatory clearance in February and will be followed by a potential Phase 1b trial in asthma and a Phase 2 trial in COPD (pending data from the Phase 1 trial). Key milestones in 2024 and 2025 include:

  - Interim Phase 1 PK and safety in healthy volunteers expected in 2H 2024, ahead of prior guidance
  - Initial proof-of-concept data in asthma expected 1H 2025
  - Proof-of-concept clinical trial in patients with COPD expected to initiate in 2025, pending positive data from Phase 1 trial and regulatory clearance

- **Early-stage programs progressing to candidate selection:** Apogee's earlier-stage programs, APG990 and APG222, utilize advanced antibody engineering to target OX40L and both IL-13 and OX40L, respectively, and are initially being developed for the treatment of 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. 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.

  - Candidate nomination for APG990 anticipated in 2024 and Phase 1 initiation in healthy volunteers in 2025
  - Apogee plans to provide more detailed updates on its earlier pipeline programs and combination strategy in an R&D Day in Q4 2024 to support its vision of future I&I therapeutics

Fourth Quarter and Full Year 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $395.5 million as of December 31, 2023, compared to $151.9 million as of December 31, 2022. Based on current operating plans, Apogee expects its existing cash, cash equivalents and marketable securities will enable the company to fund its operating expenses into 4Q 2026.

R&D Expenses: Research and development (R&D) expenses were $29.0 million for the quarter ended December 31, 2023, and $68.4 million for the year ended December 31, 2023, compared to $12.2 million for the quarter ended December 31, 2022, and $27.8 million for the period from February 4, 2022 (inception) to December 31, 2022. R&D expenses increased primarily due to further development of Apogee's APG777 and APG808 programs and advancement of its pipeline, as well as increases in personnel costs, including equity-based compensation expense, associated with the growth of its R&D team.

G&A Expenses: General and administrative (G&A) expenses were $8.2 million for the quarter ended December 31, 2023, and $24.6 million for the year ended December 31, 2023, compared to $1.9 million for the quarter ended December 31, 2022, and $2.9 million for the period from February 4, 2022 (inception) to December 31, 2022. G&A expenses increased primarily due to increases in personnel costs, including equity-based compensation, and legal and professional services, all of which were the result of the expansion of Apogee's operations to support the growth in its business and the cost of operating as a public company.

Net Loss: Net loss was $31.7 million for the quarter ended December 31, 2023, and $84.0 million for the year ended December 31, 2023, compared to a net loss of $14.0 million for the quarter ended December 31, 2022 and $39.8 million for the period from February 4, 2022 (inception) to December 31, 2022. Net loss increased primarily as a result of higher R&D and G&A operating expenses as described above, partially offset by higher interest income.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology indications with high unmet need. 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. The company's two most advanced programs are APG777 and APG808, which are being initially developed for the treatment of AD and COPD, respectively. 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: the efficacy, safety, tolerability, PK and PD profile of APG777, the potential dosing regimen of APG777, the potential superiority of APG777 compared to current therapies, Apogee's expectations regarding plans for Apogee's current and future product candidates and programs, Apogee's plans for Apogee's current and future clinical trials, including a Phase 2 trial for 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 2 trial of APG777, the potential clinical benefit and half-life of APG777, APG808, APG990, APG222 and any other potential programs, Apogee's expected timing for future pipeline updates and expectations regarding the time period over which Apogee's capital resources will be sufficient to fund Apogee's anticipated operations. 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 Quarterly Report on 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on November 13, 2023, 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.

APOGEE THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except unit/share data)

	DECEMBER 31, 2023	DECEMBER 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 118,316	$ 151,890
Marketable securities	277,143	—
Prepaid expenses and other current assets	2,950	165
Total current assets	398,409	152,055
Property and equipment, net	377	—
Right-of-use asset, net	2,217	—
Other non-current assets	401	—
Total assets	$ 401,404	$ 152,055
Liabilities, preferred units and stockholders' equity/members' deficit		
Current liabilities:		
Accounts payable	$ 2,143	$ 418
Lease liability	1,101	—
Accrued expenses	17,314	9,562
Total current liabilities	20,558	9,980
Long-term liabilities:		
Lease liability, net of current	933	—
Total liabilities	21,491	9,980
Commitments and contingencies (Note 9)		
Series A Preferred Units; no units authorized, issued and outstanding at December 31, 2023; 20,000,000 units authorized, issued and outstanding as of December 31, 2022	—	28,971
Series B Preferred Units; no units authorized, issued and outstanding at December 31, 2023; 45,089,212 units authorized, issued and outstanding as of December 31, 2022	—	148,496
Stockholders' equity/members' deficit:		
Common Units; no units authorized, issued and outstanding at December 31, 2023; 5,000,000 units authorized, issued and outstanding as of December 31, 2022	—	2,251
Incentive Units; no units authorized, issued and outstanding at December 31, 2023; 12,412,473 units authorized, 9,648,374 issued and 1,625,086 outstanding as of December 31, 2022	—	2,142
Preferred Stock; 10,000,000 authorized, $0.00001 par value, no shares issued and outstanding at December 31, 2023; No shares authorized, issued and outstanding at December 31, 2022	—	—
Common Stock; 400,000,000 authorized, $0.00001 par value, 50,655,671 issued and 48,338,769 outstanding as of December 31, 2023; No shares authorized, issued and outstanding at December 31, 2022	—	—
Additional paid-in capital	503,354	—
Accumulated other comprehensive income	329	—
Accumulated deficit	(123,770)	(39,785)
Total stockholders' equity/members' deficit	379,913	(35,392)
Total liabilities, preferred units and stockholders' equity/members' deficit	$ 401,404	$ 152,055

APOGEE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands)

	YEAR ENDED DECEMBER 31, 2023	PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO DECEMBER 31, 2022
Operating expenses:		
Research and development	$ 68,424	$ 27,786
General and administrative	24,579	2,941
Total operating expenses	93,003	30,727
Loss from operations	(93,003)	(30,727)
Other income (expense), net:		
Interest income, net	9,018	92
Other financing expense, net:	—	(9,150)
Total other income (expense), net	9,018	(9,058)
Net loss	$ (83,985)	$ (39,785)

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Exhibit 99.2

Apogee Announces Positive Interim Results from Phase 1 Healthy Volunteer Trial for APG777, its Novel Half-Life Extended Anti-IL-13 Antibody for the Treatment for Atopic Dermatitis and Other Inflammatory Diseases, Exceeding its Trial Objectives Ahead of Schedule with Half-Life of Approximately 75 days

Pharmacokinetic data support potential best-in-class profile with potential for improved clinical responses from greater exposures in induction than currently available biologic therapies and maintenance dosing of every 3- or 6-months

Single dose showed deep and sustained inhibition of key atopic dermatitis biomarkers pSTAT6 and TARC for ~3 months (longest follow-up available with inhibition still ongoing at time of data cut)

APG777 was well tolerated with a favorable safety profile consistent with the anti-IL-13 class

Company plans to initiate a randomized, placebo-controlled, 16-week Phase 2 clinical trial in patients with moderate-to-severe atopic dermatitis in 1H 2024 with induction regimen designed to exceed lebrikizumab exposures by ~30-40% and every 3- or 6- month maintenance dosing

High dose concentration of 180 mg/mL will enable 44% higher dose than lebrikizumab in the same volume

Management will host a webcast and conference call today at 7:00 a.m. ET

San Francisco, CA and Waltham, MA, Month XX, 2024 – Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease, asthma and other inflammatory and immunology (I&I) indications, today announced positive interim Phase 1 data from its first-in-human study of APG777, one of its lead product candidates being developed as a frontline treatment for moderate-to-severe AD and other inflammatory diseases. Pharmacokinetic (PK) data showed a half-life of approximately 75 days across doses tested and Pharmacodynamic (PD) data showed deep and sustained inhibition of key AD biomarkers pSTAT6 and TARC for ~3 months (longest follow-up available, with inhibition still ongoing at time of the data cut).

Results from the trial exceeded the Company's trial objectives and support the potential for APG777, a novel anti-IL-13 antibody, to optimize exposure levels in 16-week induction and be dosed once every three or six months in maintenance. These findings represent the potential for improved clinical responses from greater exposures in induction and significantly less frequent dosing in maintenance compared to currently approved biologic therapies, which are dosed at every two to four weeks, a potential major advancement for patients with AD and other inflammatory diseases. APG777, in single doses up to 1,200mg and multiple doses of 300mg, was well tolerated and showed a favorable safety profile, in line with the existing body of third-party evidence for the safety of the anti-IL-13 class. Based on these data, the company plans to initiate a randomized, placebo-controlled, Phase 2 clinical trial in patients with moderate-to-severe AD in the first half of 2024 ahead of schedule.

"The positive PK, PD and safety findings from our Phase 1 trial mark the first clinical data ahead of schedule from our portfolio of potentially differentiated biologics and underscore the promising potential of APG777 to offer patients a transformational therapy that could drive improved clinical responses than the current standard of care and extend dosing to every three or six months," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "We are excited to embark on the next phase of development for APG777, with plans to initiate our Phase 2 clinical trial in the first half of this year while rapidly progressing the rest of our pipeline forward. At Apogee, we refuse to stop at good enough and are dedicated to advancing innovative solutions for patients. Today's announcement brings us an important step closer to achieving this goal."

"Currently approved therapies for atopic dermatitis and other immunology indications typically call for injections every two to four weeks, which can lead to poor treatment adherence and long-term disease control," said Jonathan Silverberg, MD, PhD, MPH, Professor of Dermatology at The George Washington University School of Medicine and Health Sciences. "I am very encouraged by the initial data from this study, which demonstrate the potential for APG777 as a well-tolerated treatment with a half-life that would support less frequent injections."

"Significant unmet need remains for patients with moderate-to-severe AD, many of whom continue to have symptomatic disease on current therapies," said Emma Guttman-Yassky, MD, PhD, the Waldman Professor of Dermatology and Immunology and Health System Chair of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City. "APG777's Phase 2 trial will test an important hypothesis, greater inhibition of the pathway during induction, to see if improved clinical responses can be delivered for patients living with AD."

APG777 is a novel, subcutaneous extended half-life monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD. In our head-to-head preclinical studies, APG777 demonstrated equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling. Based on its potentially best-in-class PK profile, APG777 has the potential for improved clinical responses from greater exposures of drug in induction and dosing as infrequently as once every three or six months. AD is a chronic inflammatory skin disorder which can lead to sleep disturbance, psychological distress, elevated infection risk and chronic pain, all of which significantly impact quality of life. Today's treatments are associated with many challenges, including frequent injection regimens that can lead to poor patient compliance. APG777 represents the first clinical-stage product candidate from the company's strategic collaboration with Paragon Therapeutics, Inc., an innovative discovery engine for biologics.

Key Phase 1 Interim Findings

The Phase 1 trial is a first-in-human, randomized, double-blind, placebo-controlled study designed to evaluate safety and PK of APG777 in healthy volunteers. The study enrolled 40 healthy adult participants into three single-ascending dose (SAD) and two multiple-ascending dose (MAD) cohorts. Doses of subcutaneous APG777 evaluated in the study included 300mg, 600mg and 1,200mg. Detailed findings from the SAD portion and interim results from MAD portion of the Phase 1 trial are as follows:

- **PK differentiation supports further development of APG777 as a treatment for moderate-to-severe AD and other inflammatory diseases**
    - Potentially best-in-class PK profile, including a half-life of approximately 75 days, supporting:
        - Testing higher exposures of drug in induction to potentially achieve improved clinical responses
        - Testing of maintenance dosing of every 3- or 6-months, representing 2-4 injections per year compared to the current treatment paradigm of 13-26 injections per year
    - Dose-proportional increases in serum concentrations and key parameters (e.g., C_{max}, AUC) were observed in the Phase 1 trial
    - PK was consistent across subjects with low variability
- **Single doses of APG777 demonstrated a deep and sustained effect on PD markers for ~3 months (longest follow-up available with inhibition still ongoing at time of data cut)**
    - Single doses of APG777 suppressed pSTAT6, one of the first downstream markers of IL-13 pathway inhibition, with near-complete inhibition for ~3 months

- Single doses of APG777 suppressed TARC, an inflammatory mediator and the most strongly correlated biomarker to AD severity, with deep and sustained inhibition for ~3 months

- **Well tolerated across all dose groups.** Single doses of APG777 up to 1,200mg and multiple doses of 300 mg were well tolerated with a favorable safety profile consistent with the existing third-party data supporting the safety of the anti-IL-13 class.
    - The most common treatment-emergent adverse events (TEAEs) were vascular access site pain, vessel puncture site bruise, headache, and vascular access bruising
        - 60% of participants observed at least one TEAE; 15% of participants observed at least one drug-related AE
    - There were no Grade 3 TEAEs or severe adverse events (SAEs). No AEs led to study discontinuation

"The interim results from this Phase 1 trial are tremendously encouraging for APG777's potential to meaningfully improve the standard of care for patients with moderate-to-severe AD. On behalf of the entire Apogee team, I'd like to extend our heartfelt gratitude to the volunteers, investigator, and the study team for their support in the successful execution of this important trial," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee Therapeutics. "We look forward to rapidly advancing APG777 into Phase 2 clinical trials in AD and other inflammatory conditions."

Phase 2 trial in AD

Following today's positive interim results, Apogee plans to advance APG777 into a randomized, placebo-controlled, 16-week Phase 2 clinical trial in patients with moderate-to-severe AD.

- **Phase 2 AD trial is expected to initiate in the 1H of 2024 with 16-week topline data from Part A expected in 2H 2025**
    - Part A is expected to enroll approximately 110 patients randomized 2:1 to APG777 vs placebo with primary endpoint of mean percentage changes in EASI score from baseline to Week 16
    - Part B of the Phase 2 trial is a randomized, placebo-controlled dose optimization with approximately 360 patients randomized 1:1:1:1 to high, medium, or low dose APG777 vs placebo with primary endpoint of mean percentage changes in EASI score from baseline to Week 16
    - All patients benefiting from treatment will continue to APG777 maintenance, which will evaluate 3- to 6-month dosing
- **Integrated design expected to provide for significant timeline acceleration by combining Ph2a and Ph2b elements into a single study protocol**
    - All Part A sites are also expected to participate in Part B, avoiding delays for site startup between the two parts
- **Doses in the Phase 2 trial are enabled by APG777's potentially best-in-class PK profile, extended half-life, and high-concentration formulation**
    - 180 mg/mL formulation enables 44% higher dose of APG777 vs lebrikizumab in the same volume
- **APG777 Phase 2 induction regimen is designed to exceed lebrikizumab (an IL-13 inhibitor with an overlapping epitope with APG777) exposures by ~30 to 40% with potential for improved clinical responses and maintenance regimen is designed to equal lebrikizumab's exposures**
    - In Phase 3 studies, ~30% higher exposure seen in lebrikizumab low bodyweight group resulted in numerically higher efficacy than the overall study population across all key endpoints, including EASI-75 and more stringent endpoints such as EASI-90 and IGA 0/1

- ~30-40% higher induction exposures for APG777 than lebrikizumab are based on a planned six injection induction regimen given in the first sixteen weeks of APG777 treatment. This is approximately half as many of the 11 injections of lebrikizumab given during the same period

- At 52 weeks, exposures of APG777 dosed every three months are designed to exceed those of lebrikizumab and exposures of APG777 dosed every six months are designed to equal those of lebrikizumab

Conference Call and Webcast

Apogee will host a conference call and webcast today, March 5, 2024, at 7:00 a.m. ET to discuss the APG777 Phase 1 interim results. A live webcast of the call will be available on the Investor Relations page of Apogee's website at https://investors.apogeetherapeutics.com/news-events/events. The webcast will be made available for replay on the company's website following completion of the event.

About APG777

APG777 is a novel, subcutaneous extended half-life monoclonal antibody targeting IL-13 for the potential treatment of atopic dermatitis (AD). In head-to-head preclinical studies, APG777 showed equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling. AD is a chronic inflammatory skin disorder that affects approximately 40 million adults and 18 million children in the United States, France, Germany, Italy, Japan, Spain and the United Kingdom, 40 percent of which have moderate-to-severe disease. Based on initial clinical data, the company may initiate a Phase 2 trial in asthma 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, eosinophilic esophagitis and prurigo nodularis.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology indications with high unmet need. 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. The company's two most advanced programs are APG777 and APG808, which are being initially developed for the treatment of AD and COPD, respectively. 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.

Financial Disclosures

Dr. Silverberg and Dr. Guttman- Yassky receive financial compensation as a scientific advisor for Apogee.

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: the efficacy, safety, tolerability, PK and PD profile of APG777, the potential dosing regimen of APG777, the potential superiority of APG777 compared to current therapies, our expectations regarding plans for our current and future product candidates and programs, our plans for our current and future clinical trials, including a Phase 2 trial for APG777, our plans for clinical trial design, the anticipated timing of the initiation of and results from our clinical trials, including data from our Phase 2 trial of AP777, and the potential clinical benefit and half-life of APG777. 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 our preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of our 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 our Quarterly Report on 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on November 13, 2023 , 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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