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): May 13, 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 2.02 Results of Operations and Financial Condition.

On May 13, 2024, Apogee Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024.

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, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Earnings Press Release, dated May 13, 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: May 13, 2024

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

Exhibit 99.1

Apogee Therapeutics Highlights Pipeline Progress and Reports First Quarter 2024 Financial Results

Initiated a Phase 2 clinical trial of APG777, a subcutaneous half-life extended monoclonal antibody targeting IL-13, in patients with moderate-to-severe atopic dermatitis, with 16-week proof-of-concept data from Part A of the trial expected in 2H 2025

First participant dosed in Phase 1 healthy volunteer clinical trial of APG808, a subcutaneous half-life extended monoclonal antibody targeting IL-4Rα, for the treatment of chronic obstructive pulmonary disease and other inflammatory diseases with interim Phase 1 data expected in 2H 2024

Nominated development candidate for APG990, a subcutaneous half-life extended monoclonal antibody targeting OX40L, with a Phase 1 trial in healthy volunteers expected to initiate in 2H 2024

$816 million cash, cash equivalents and marketable securities with runway into 2028

SAN FRANCISCO, CA and WALTHAM, MA, May 13, 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 first quarter financial results.

"I am proud of the continued momentum our team has achieved this quarter, executing against our goals and successfully bringing our programs forward ahead of schedule," said Michael Henderson, MD, Chief Executive Officer of Apogee. "We continue to maintain that pace of progress with the selection of our development candidate for APG990 and now plan to initiate a Phase 1 trial in healthy volunteers by the end of the year. We commenced dosing of the first healthy participants in our second clinical program, APG808, and expect an interim readout in the second half of this year. Following that readout, we're planning a Phase 1b readout for APG808 in asthma to follow in the first half of 2025 that is designed to determine the doses to then take into a Phase 2 trial in COPD in the same year. We are on track to dose the first patient in the APG777 Phase 2 trial in patients with moderate-to-severe AD in the first half of this year. Additionally, on the heels of our successful interim Phase 1 APG777 data readout, we raised $483 million in an upsized public offering providing capital into 2028."

Pipeline and Corporate Highlights and Upcoming Milestones

- **Initiated Phase 2 APG777 clinical trial**: APG777 is a novel, subcutaneous (SQ) half-life extended monoclonal antibody (mAb) targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD.
    - The company has commenced enrollment of patients for the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD in the first half of 2024, with 16-week proof-of-concept data from Part A of the trial expected in 2H 2025.
    - The trial is designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. The primary endpoint of each part of the study is mean percentage changes in EASI score from baseline to Week 16.
    - Initiation of a Phase 2 APG777 trial in asthma is expected to commence in 2025.
- **First participant dosed in APG808 Phase 1 trial:** Apogee's second program, APG808, is a novel, SQ half-life extended 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 compared to picomolar affinity in the first generation mAb, DUPIXENT, and has demonstrated similar inhibition to DUPIXENT across three in vitro assays that measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion).

- In March 2024, Apogee initiated dosing of healthy volunteers in its Phase 1 clinical trial. The company expects to share initial data in the second half of 2024 followed by a Phase 1b clinical trial in asthma with data expected in the first half of 2025 and initiation of a COPD trial in the same year.

- **APG990 development candidate selected**: Apogee has selected a development candidate for its APG990 program, 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 both Type 1 and Type 2 inflammation. With current approved biologics only targeting Type 2 inflammation (IL-13/IL4Rα) in AD, OX40L could represent another therapeutic option for patients, especially the portion of patients who do not benefit from currently available treatments. APG990 has been engineered to have differentiated attributes, including an extended half-life, which we expect will result in a more favorable dosing schedule of every three or six months. The company is also interested in testing the hypothesis that combining APG990 with APG777 will result in more extensive inhibition of the inflammatory cascade (Type 1 and Type 2 inflammation) than either approach alone. The company plans to present additional data on this at its R&D Day in the fourth quarter of this year.

    - Initiation of a Phase 1 APG990 trial in healthy volunteers is expected to begin ahead of schedule and is now expected in the second half of 2024.

- **Completed $483 million upsized public offering**: In March, the company closed on an upsized public offering of 7,790,321 shares of common stock, including the full exercise of the underwriters' option to purchase up to 1,016,128 additional shares, at a public offering price of $62.00 per share. The aggregate gross proceeds to Apogee from the offering were approximately $483.0 million before deducting underwriting discounts and commissions and other offering expenses payable by Apogee.

First Quarter Financial Results

- **Cash Position**: As of March 31, 2024, Apogee had cash, cash equivalents and marketable securities of $816.2 million. Apogee expects that its existing total cash will enable it to fund its current operating expenses into the first quarter of 2028.

- **Research & Development (R&D) Expenses**: R&D expenses for the first quarter of 2024 were $28.7 million, compared to $8.5 million for the first quarter of 2023. R&D expenses increased primarily due to further development of the company's APG777 and APG808 programs and advancement of its pipeline into clinical trials, as well as increases in personnel costs, including equity-based compensation expense, associated with the growth of its R&D team.

- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter of 2024 were $9.5 million, compared to $4.2 million for the first quarter of 2023. G&A expenses increased primarily due to increases in personnel costs, including equity-based compensation, associated with the growth of the company's G&A team, as well as increased costs related to being a public company, including for legal, IT and professional services, and to support the growth of the business.

- **Net Loss**: Net loss for the first quarter of 2024 was $32.1 million, compared to $12.5 million net loss for the first quarter of 2023 . Net loss increased primarily as a result of higher R&D and G&A 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, COPD, and asthma, 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: Apogee's expectations regarding plans for its current and future product candidates and programs, its plans for Apogee's current and future clinical trials, including a Phase 2 trial for APG777 in asthma, Phase 1 trials of APG808, and a Phase 1 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 2 trial of APG777 and Apogee's Phase 1 trial of APG808, the potential clinical benefit and half-life of APG777, APG808, APG990 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 Annual Report on 10-K for the year period ended December 31, 2023, filed with the SEC on March 5, 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.

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

	MARCH 31, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 485,457	$ 118,316
Marketable securities	330,739	277,143
Prepaid expenses and other current assets	4,412	2,950
Total current assets	820,608	398,409
Property and equipment, net	699	377
Right-of-use asset, net	1,951	2,217
Other non-current assets	401	401
Total assets	$ 823,659	$ 401,404
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	4,302	$ 2,143
Lease liability	1,141	1,101
Accrued expenses	16,108	17,314
Total current liabilities	21,551	20,558
Long-term liabilities:		
Lease liability, net of current	630	933
Total liabilities	22,181	21,491
Stockholders' Equity:		
Common Stock; $0.00001 par value, 400,000,000 authorized, 58,456,027 issued and 56,367,802 outstanding as of March 31, 2024; 400,000,000 authorized, 50,655,671 issued and 48,338,769 outstanding as of December 31, 2023	1	-
Additional paid-in capital	957,518	503,354
Accumulated other comprehensive (loss) income	(177)	329
Accumulated deficit	(155,864)	(123,770)
Total stockholders' equity	801,478	379,913
Total liabilities and stockholders' equity	$ 823,659	$ 401,404

APOGEE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(UNAUDITED)
(In thousands, except share and per share data)

	THREE MONTHS ENDED MARCH 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 28,716	$ 8,455
General and administrative	9,465	4,203
Total operating expenses	38,181	12,658
Loss from operations	(38,181)	(12,658)
Other income, net:		
Interest income, net	6,087	133
Total other income, net	6,087	133
Net loss	$ (32,094)	$ (12,525)

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