



# Apogee Therapeutics Provides Pipeline Progress and Reports Full Year 2024 Financial Results

March 3, 2025

*Accelerated execution of Phase 2 APEX clinical trial for APG777, with Part A over-enrolled and Part B initiated ahead of schedule; topline Part A 16-week data expected mid-2025*

*APG279 (APG777 + APG990) Phase 1b head-to-head study vs. DUPIXENT supported by positive APG990 interim Phase 1 results, which exceeded trial objectives and demonstrated potential for three- and six-month dosing in combination with APG777; APG279 readout expected in second half of 2026*

*\$731.1 million cash, cash equivalents and marketable securities with runway into Q1 2028*

SAN FRANCISCO and BOSTON, March 03, 2025 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing novel biologics with the potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, eosinophilic esophagitis (EoE), chronic obstructive pulmonary disease (COPD) and other I&I indications, today provided pipeline progress and reported full year 2024 financial results.

"We achieved significant progress across our pipeline in 2024 and are well-positioned to continue executing rapidly on our mission to bring transformative, potentially best-in-class therapies to patients with I&I diseases," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "We kicked off 2025 by over-enrolling Part A and dosing the first patient in the Part B portion of our Phase 2 APEX clinical trial for APG777 in AD, well ahead of schedule and we are on track for our critical 16-week readout for APG777 in mid-2025. Our positive readout today from the Phase 1 trial of APG990 in healthy volunteers enables our combination study of APG777 + APG990, which we have named APG279, versus DUPIXENT this year following regulatory submissions, with this important dataset expected in the second half of 2026. With a strong cash position and several meaningful catalysts expected, we are looking forward to an exciting and productive 2025."

## **Pipeline Highlights and Upcoming Milestones**

- **Company continues to execute on APG777 monotherapy program in AD as well as initial expansion indications in asthma and EoE:** APG777 is a novel, subcutaneous (SQ), extended half-life monoclonal antibody (mAb) targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD.
  - At its December 2024 R&D Day, the [company reported](#) updated data from its Phase 1 APG777 trial, out to 12 months, including a half-life of 77 days, which continue to support a potentially best-in-class profile. In the updated dataset, safety was consistent with prior results, and APG777 demonstrated a favorable pharmacodynamic (PD) profile showing near complete inhibition of pSTAT6 for up to 12 months after a single administration and sustained TARC inhibition.
  - The data support Apogee's ongoing Phase 2 clinical trial of APG777 in AD and support the potential for improved clinical responses from greater exposures in induction and maintenance dosing of every three- and six-months. In February 2025, the company announced that Part A of the trial had exceeded enrollment expectations and the first patient was dosed in Part B – both milestones completed ahead of schedule.
    - The company expects to report 16-week topline data from the Part A portion of the trial mid-2025.
  - Apogee plans to initiate a Phase 1b trial in asthma the first half of 2025 followed by a Phase 2b trial in asthma in the second half of 2025 with data expected in 2026.
  - The company also plans to initiate a Phase 2 trial in EoE in 2026.
- **APG279 (APG777 + APG990) Phase 1b head-to-head study against DUPIXENT now supported by positive, interim Phase 1 results for APG990 and completion of a combination toxicology study:** APG990 is a novel, SQ, half-life extended monoclonal antibody (mAb), and the combination with APG777 offers the potential for improved clinical responses over monotherapy across a variety of I&I diseases while Apogee's approach of coformulating two extended half-life mAbs holds the potential for best-in-class dosing. Today, the company reported positive interim results in the Phase 1 first-in-human study of APG990, which is designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of single-ascending doses (SAD) of APG990 in healthy volunteers. Key findings from the study include:
  - PK profile includes half-life of approximately 60 days; PK profile supports the potential for a single 2 mL co-formulated injection of APG279 administered every three- and six-months in maintenance.
  - APG990 was well tolerated across all dose groups with a favorable safety profile.
- Based on these data, Apogee plans to initiate its first combination trial in 2025 – a Phase 1b trial designed to evaluate the safety, PK, PD and efficacy of APG279 against DUPIXENT in patients with moderate-to-severe AD, with interim readout expected in the second half of 2026.

- **Progress in respiratory indications continues with planned combination approach of 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 of APG333 in healthy volunteers is underway, with data expected in the second half of 2025.
  - 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.
- **Positive interim data for APG808 Phase 1 trial reported, supporting the potential for two- to three-month dosing and demonstrating deep and sustained inhibition of biomarkers:** APG808 is a novel SQ extended half-life mAb targeting IL-4R $\alpha$ , a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding affinity for IL-4R $\alpha$  as a 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.
  - At its December 2024 R&D Day, the [company reported](#) interim data from all four SAD cohorts in the Phase 1 healthy volunteer trial. APG808 demonstrated a potential best-in-class PK profile, including a half-life of approximately 55 days, and single doses of APG808 demonstrated deep and sustained effect on PD markers out to ~3 months (which was the longest follow-up available at the time of data cut). APG808 was well tolerated in the study.
  - Apogee is also evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

## **Full Year 2024 Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities were \$731.1 million as of December 31, 2024, compared to \$395.5 million as of December 31, 2023. 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 the first quarter of 2028.
- **R&D Expenses:** Research and development (R&D) expenses were \$167.9 million for the year ended December 31, 2024, compared to \$68.4 million for the year ended December 31, 2023. R&D expenses increased primarily due to continued development of the company's APG777, APG990/APG777 + APG990, and APG333/APG777 + APG333 programs and advancement of its pipeline into clinical trials, as well as increases in personnel related expenses including equity-based compensation expense, associated with the growth of its R&D team.
- **G&A Expenses:** General and administrative (G&A) expenses were \$49.0 million for the year ended December 31, 2024, compared to \$24.6 million for the year ended December 31, 2023. G&A expenses increased primarily due to increases in personnel related expenses including equity-based compensation expenses, primarily driven by increased headcount and an increase in the fair value of equity awards granted. These increases are the result of the company's expansion of operations to support the growth in its business and the costs of operating as a public entity.
- **Net Loss:** Net loss was \$182.1 million for the year ended December 31, 2024, compared to a net loss of \$84.0 million for the year ended December 31, 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 advancing novel biologics with potential for differentiated efficacy and dosing in the largest I&I markets, including for the treatment of AD, asthma, EoE, 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 <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; the anticipated timing of the initiation of its clinical trials, including the Phase 1b trial of APG279 (the combination of APG777 and APG990), the Phase 1b and 2b trials of APG777 in asthma, the Phase 2 trial of APG777 in EoE, and the Phase 1b trial of APG333 in asthma; the expected timing of and results from its clinical trials, including data from its Phase 2 trial of APG777, Phase 1b trial of APG279, Phase 1 trial of APG333, Phase 1b trial of APG808, the potential combination of APG777 and APG333; planned clinical trial designs; its plans for current and future clinical trials; the potential clinical benefit and half-life of APG777, APG990, APG333, APG808, Apogee's other product candidates, including combination therapies, and any other potential programs; its expected timing for future pipeline updates and expectations regarding the time period over which Apogee's capital resources will be sufficient to fund its 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, 2024, filed with the SEC on November 12, 2024, and subsequent disclosure documents the company 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, 2024	DECEMBER 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 141,789	\$ 118,316
Marketable securities	378,864	277,143
Prepaid expenses and other current assets	9,060	2,950
Total current assets	529,713	398,409
Long-term marketable securities	210,416	—
Property and equipment, net	1,959	377
Right-of-use asset, net	11,365	2,217
Other non-current assets	498	401
Total assets	\$ 753,951	\$ 401,404
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,071	\$ 2,143
Lease liability	3,234	1,101
Accrued expenses	24,255	17,314
Total current liabilities	28,560	20,558
Long-term liabilities:		
Lease liability, net of current	8,597	933
Total liabilities	37,157	21,491
Stockholders' equity:		
Common Stock; \$0.00001 par value, 400,000,000 authorized, 59,478,725 issued and 58,062,898 outstanding as of December 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	1,021,794	503,354
Accumulated other comprehensive income	915	329
Accumulated deficit	(305,916)	(123,770)
Total stockholders' equity	716,794	379,913
Total liabilities and stockholders' equity	\$ 753,951	\$ 401,404

**APOGEE THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands)

	<b>YEAR ENDED DECEMBER 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses:		
Research and development	\$ 167,865	\$ 68,424
General and administrative	49,005	24,579
Total operating expenses	<u>216,870</u>	<u>93,003</u>
Loss from operations	(216,870)	(93,003)
Other income, net:		
Interest income, net	34,742	9,018
Total other income, net	<u>34,742</u>	<u>9,018</u>
Net loss before taxes	(182,128)	(83,985)
Provision for income taxes	(18)	—
Net loss after taxes	<u>\$ (182,146)</u>	<u>\$ (83,985)</u>

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