Apogee Therapeutics Provides Pipeline Progress and Reports Second Quarter 2025 Financial Results

August 11, 2025

Positive 16-week data from APEX Phase 2 Part A met all primary and key secondary endpoints for APG777, a potentially best-in-class anti-IL-13 antibody, in moderate-to-severe atopic dermatitis

APEX Part A testing every 3- or 6-month maintenance dosing, a significant improvement versus standard of care which is dosed every two weeks, is ongoing with 52-week readout anticipated in 1H 2026

Driven by strong enrollment, APEX Phase 2 Part B of APG777 readout accelerated to mid-2026

First patient dosed in Phase 1b head-to-head trial of APG279 (IL-13 + OX40L) vs. DUPIXENT in atopic dermatitis, with readout expected in 2H 2026

$621.2 million cash, cash equivalents and marketable securities supports runway into Q1 2028

SAN FRANCISCO and BOSTON, Aug. 11, 2025 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc., (Nasdaq: APGE), a clinical-stage biotechnology company advancing optimized, novel biologics with potential for best-in-class profiles in the largest inflammatory and immunology (I&I) markets, today provided pipeline progress and reported second quarter 2025 financial results.

"We are proud of the strong execution across our pipeline in the first half of 2025, highlighted by the recent 16-week Phase 2 Part A topline readout of the APEX clinical trial, in which APG777 met the primary and key secondary endpoints and demonstrated ability to reduce injection burden for patients. These results reinforce APG777's potentially best-in-class profile for moderate-to-severe AD as the only biologic being tested out to every 3- and 6-month dosing in maintenance," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "We look forward to continued evaluation of APG777 in Part B of APEX, where we are testing APG777 at multiple doses to identify the dose to take forward into Phase 3 studies which we plan to launch next year. Driven by the positive Part A topline results and strong enrollment, we have accelerated readout timing for Part B to mid-2026. Our momentum extends across our broader pipeline, including the recent initiation of our Phase 1b head-to-head trial of APG279 vs. DUPIXENT in atopic dermatitis, which remains on track to readout in the second half of 2026, and the upcoming readout of healthy volunteer data for APG333 expected in the fourth quarter of this year. With a strong cash position and several potentially value creating clinical milestones expected over the coming quarters, we are well positioned to advance our mission of reshaping the standard of care for patients living with I&I diseases."

"The enthusiasm we're receiving from patients and physicians has been validating for our program and reinforces our confidence in APG777's potential," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "We're encouraged by the strength of the topline data from the APEX Part A study and look forward to sharing additional results at upcoming medical conferences. Today's approved treatments for atopic dermatitis are associated with an injection burden that can limit disease control and long-term adherence for many patients. In our Part A study, we tested 4 dosing days compared to 9 for standard of care during the first 16-week induction period and we look forward to proving our dosing advantage in maintenance with the potential for 2-4 injections per year compared to 26 for the standard of care. We have seen from other diseases, like psoriasis, the meaningful impact reduced injection burden provides to patients and physicians, and we look forward to reading out the 52-week maintenance portion of APEX Part A in the first half of 2026."

Pipeline Highlights and Upcoming Milestones

- **Apogee reported positive 16-week Part A topline results from Phase 2 APEX trial, underscoring APG777's potential as a best-in-class monotherapy:** 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 atopic dermatitis (AD).
    - APEX Part A met its primary endpoint, with APG777 demonstrating an Eczema Area and Severity Index (EASI) reduction from baseline of 71.0% compared to placebo at 33.8% ($p < 0.001$). APG777 also demonstrated absolute EASI-75 of 66.9% compared to 24.6% on placebo ($p < 0.001$). Several key secondary endpoints were in line with the standard of care, including Validated Investigator Global Assessment (vIGA) 0/1 of 34.9% compared to placebo of 17.3% ($p < 0.05$), and EASI-90 of 33.9% compared to placebo of 14.7% ($p < 0.05$). APG777 was well tolerated, with a safety profile consistent with other agents in the class. In TEAEs experienced by 5% or more of patients, only non-infective conjunctivitis was more common in APG777 treated patients, showed no association with drug exposure, and led to no dose modifications, interruptions, or discontinuations. Patients received an induction regimen dosing of 4 days compared to 9 dosing days for standard of care.
    - The APEX Part A maintenance phase is testing dosing every 3- and 6-months and may support long-term disease control with just 2-4 injections per year, compared to 26 with the current standard of care. 52-week data from APEX Part A is expected in the first half of 2026.

- APEX Part B is testing three doses of APG777 versus placebo, including a high dose regimen modeled to have approximately 90-100% greater exposure than EBGLYSS. Enrollment has remained strong in this global trial, and the 16-week Part B readout has been accelerated to mid-2026.
- Pending results from Part A maintenance, Part B induction data and regulatory feedback, the company plans to initiate Phase 3 trials of APG777 in 2026.

- **Continued progress for APG777 in expanded indications expected in 2025 and 2026**

  - The Phase 1b trial of APG777 in patients with mild-to-moderate asthma is ongoing, with readout expected in the first half of 2026. The primary endpoint of the trial is safety and tolerability, with secondary endpoints exploring pharmacokinetics (PK) and fractional exhaled nitric oxide concentration (FeNO) suppression of APG777.
  - Apogee plans to conduct Phase 2b trials in asthma and eosinophilic esophagitis (EoE) with trial designs informed by APEX Part B dose optimization as well as the Phase 1b results in asthma. Apogee expects to announce plans for these Phase 2b trials in 2026.

- **First patient dosed in APG279 (APG777 + APG990) Phase 1b head-to-head study against DUPIXENT**: APG279 is the company's first combination treatment, combining APG777 and APG990. APG990 is a novel, SQ, extended half-life mAb targeting OX40L, and the combination with APG777, offers the potential for improved clinical responses over monotherapy across a variety of I&I diseases by targeting Type 1, 2 and 3 inflammation. Apogee's approach of co-formulating two extended half-life mAbs also provides the potential for first-in-class and best-in-class dosing.

  - In July 2025, Apogee announced that the first patient was dosed in its first-in-class combination trial, a Phase 1b study designed to evaluate safety, PK, pharmacodynamics and efficacy of APG279 vs. DUPIXENT in patients with moderate-to-severe AD. Readout is expected in the second half of 2026.

- **Progress continues in 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 fourth quarter of 2025.
  - Pending results of the trial and results from the APG777 Phase 1b asthma trial and APEX Part B, Apogee expects to announce plans for its combination approach of APG777 + APG333 in respiratory conditions.

Second Quarter 2025 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $621.2 million as of June 30, 2025, compared to $681.4 million as of March 31, 2025. Based on current operating plans, Apogee expects that 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 $55.7 million for the quarter ended June 30, 2025, compared to $33.2 million for the quarter ended June 30, 2024. R&D expenses increased primarily due to further development of our APG777 program, as well as increases in personnel-related expenses and equity-based compensation associated with the growth in the company's R&D team.

- **G&A Expenses**: General and administrative (G&A) expenses were $17.5 million for the quarter ended June 30, 2025, compared to $10.9 million for the quarter ended June 30, 2024. G&A expenses increased primarily due to increases in personnel-related expenses and equity-based compensation, 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.

- **Net Loss**: Net loss was $66.1 million for the quarter ended June 30, 2025, compared to a net loss of $33.8 million for the quarter ended June 30, 2024. Net loss increased primarily as a result of higher R&D and G&A expenses as described above.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company advancing optimized, novel biologics with potential for best-in-class profiles in the largest 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. 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 profiles 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 2 trial of APG777 in asthma, the Phase 2 trial of APG777 in EoE and the Phase 3 trial of APG777; the expected timing of and results from its clinical trials, including data from Part A and Part B of its APEX Phase 2 trial of APG777 in AD, Phase 1b trial of APG279 in AD, Phase 1 trial of APG333 in healthy volunteers, Phase 1b trial of APG777 in asthma; its planned clinical trial designs; its plans for current and future clinical trials; the potential clinical benefit and half-life, PK profile and dosing regimen, and treatment outcomes of APG777, APG279, APG990, APG333, APG777+APG333, APG808, Apogee's other product candidates, including combination therapies, and any other potential programs; its planned business strategies; its expected timing for future pipeline updates; and its expectations regarding the time period over which Apogee's capital resources will be sufficient to funds 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 Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025, Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, filed with the SEC on May 12, 2025 and subsequent disclosure documents Apogee 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 share data)

	JUNE 30, 2025	DECEMBER 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 124,192	$ 141,789
Marketable securities	381,228	378,864
Prepaid expenses and other current assets	10,702	9,060
Total current assets	516,122	529,713
Long-term marketable securities	115,769	210,416
Property and equipment, net	6,438	1,959
Right-of-use asset, net	10,586	11,365
Other non-current assets	8,857	498
Total assets	$ 657,772	$ 753,951
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,678	$ 1,071
Lease liability	4,025	3,234
Accrued expenses and other current liabilities	21,848	24,255
Total current liabilities	31,551	28,560
Long-term liabilities:		
Lease liability, net of current	6,820	8,597
Total liabilities	38,371	37,157
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common Stock; $0.00001 par value, 400,000,000 authorized, 59,587,430 issued and 58,560,525 outstanding as of June 30, 2025; 400,000,000 authorized, 59,478,725 issued and 58,062,898 outstanding as of December 31, 2024	1	1
Additional paid-in capital	1,046,066	1,021,794
Accumulated other comprehensive income	685	915

Accumulated deficit	(427,351)	(305,916)
Total stockholders' equity	619,401	716,794
Total liabilities and stockholders' equity	$ 657,772	$ 753,951

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(UNAUDITED)
(In thousands)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 55,703	$ 33,206	$ 102,090	$ 61,922
General and administrative	17,462	10,916	34,171	20,381
Total operating expenses	73,165	44,122	136,261	82,303
Loss from operations	(73,165)	(44,122)	(136,261)	(82,303)
Other income, net:				
Interest income, net	7,141	10,306	14,981	16,393
Total other income, net	7,141	10,306	14,981	16,393
Net loss before taxes	(66,024)	(33,816)	(121,280)	(65,910)
Provision for income taxes	(72)	—	(155)	—
Net loss after taxes	$ (66,096)	$ (33,816)	$ (121,435)	$ (65,910)

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