Apogee Therapeutics Provides Pipeline Progress and Reports Third Quarter 2024 Financial Results

November 12, 2024 12:00 PM EST

Continued execution across all programs, including positive results up to nine months from APG777 Phase 1 trial that continue to support potential best-in-class profile

On track to report Phase 2 Part A data for APG777 in 2H 2025, interim Phase 1 data for APG808 in 4Q 2024 and interim Phase 1 data for APG990 in 1H 2025

APG333 development candidate selected and accelerating initiation of Phase 1 in late 2024 or early 2025; potential to offer best-in-class combination efficacy across multiple respiratory indications

Plans advancing for combination studies, starting with the first clinical trial of the APG777 and APG990 combination for the treatment of AD in 2025

$754 million cash, cash equivalents and marketable securities with runway into 2028

Virtual R&D Day to be held December 2, 2024 at 10am ET

SAN FRANCISCO and WALTHAM, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- 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) and other I&I indications, today reported pipeline highlights and third quarter financial results.

"We continue to execute across our portfolio and advance potentially transformative therapies for patients living with I&I diseases by positioning our pipeline to achieve potential best-in-class efficacy and dosing," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "Over the past year, we demonstrated significant progress advancing three programs – soon to be four – into the clinic and our lead program, APG777, into Phase 2 trials. Importantly, we remain in a very strong cash position providing for runway into 2028 and look forward to sharing more details and progress on our pipeline and combination strategy during our R&D Day on December 2nd."

Pipeline Highlights and Upcoming Milestones

- **Results up to 9 months from the APG777 Phase 1 trial reported at the American College of Allergy, Asthma and Immunology's 2024 Annual Scientific Meeting (ACAAI) continue to support potential best-in-class profile, including a half-life of approximately 75 days:** 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 ACAAI, Apogee reported updated data from its Phase 1 trial in healthy volunteers, including findings from the 40 enrolled participants across three single-ascending dose cohorts, now with nine months of follow-up, and two multiple-ascending dose cohorts, now with six months of follow-up. Findings demonstrate that APG777, in single and multiple doses up to 1,200 mg, showed a consistent safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile following induction.
  - PD profile showed near complete inhibition of pSTAT6 and sustained TARC inhibition up to 9 months.
  - Updated data supports Apogee's ongoing Phase 2 clinical trial of APG777 in AD demonstrating potential for improved clinical responses from greater exposures in induction and maintenance dosing of every 3- or 6-months
  - The company expects to report 16-week topline data from Part A of the APG777 Phase 2 trial in the second half of 2025.
- **Phase 1 APG808 trial on track for 4Q 2024 interim data readout:** APG808 is a novel SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding affinity for IL-4Rα 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.
  - The company expects to report interim Phase 1 data for APG808 in the fourth quarter of 2024.
- **First participants dosed in Phase 1 trial of APG990:** APG990 is 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 have broader impact on the inflammatory cascade by inhibiting Type 1, Type 2 and Type 3 pathways.
  - In August 2024, Apogee initiated its Phase 1 APG990 trial, designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose trial in healthy volunteers. The study will evaluate the safety, tolerability and PK of APG990 and is expected to enroll approximately 40 healthy adults across 5 cohorts.
  - The company expects to report interim Phase 1 data for APG990 in the first half of 2025.
- **Potential to expand patient reach with best-in-class efficacy and dosing with planned APG777 and APG990 combination approach, combining IL-13 and OX40L inhibition:** Apogee plans to develop APG777 and APG990 together as a potential first-in-class coformulation combining deep and sustained inhibition of Type 2 inflammation via APG777's inhibition of IL-13 with broader inhibition of Types 1-3 inflammation through APG990's inhibition of OX40L. These combined mechanisms offer the potential for improved clinical responses over monotherapies across a variety of I&I diseases while the approach of co-formulating two extended half-life mAbs holds the potential for best-in-class dosing.
  - The company plans to initiate the first clinical trial of the APG777 and APG990 combination in 2025.
- **APG333 anti-TSLP antibody development candidate nominated:** APG333 is a novel, SQ extended half-life mAb targeting thymic stromal lymphopoietin (TSLP). TSLP is an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of I&I indications. In addition, a TSLP-targeting mAb may be used in combination with other mAbs for potentially greater efficacy in broader populations. TSLP plays important roles in Type 2 and Type 3 inflammation, particularly in both eosinophilic and non-eosinophilic inflammation. TSLP inhibition has been clinically validated, with one approved product on the market for the treatment of severe asthma without biomarker or phenotype restrictions. Based on its mechanism, TSLP inhibition could offer treatment to the approximately 40% of severe asthma patients with low Type 2 inflammation.
  - The company now plans to initiate a Phase 1 clinical trial in healthy volunteers of APG333 in late 2024 or early 2025.
  - Pending Phase 1 data, the company has the opportunity to combine APG777 with APG333, combining IL-13 and TSLP inhibition, to

drive potential best-in-class efficacy in asthma and other respiratory indications.

Corporate Highlights

- **Jeff S. Hartness appointed as Chief Commercial Officer.** In September 2024, Apogee appointed Mr. Hartness as its Chief Commercial Officer. Mr. Hartness has an extensive track record in commercial and corporate leadership and more than 25 years of experience in the biotech industry focused on product launches, market access strategy, pricing and policy.
- **Apogee Therapeutics 2024 Virtual R&D Day to be held on December 2, 2024 at 10am ET:** The company plans to highlight its progress across its pipeline and showcase its path to reshaping the standard of care in I&I by bringing forward monotherapy and combination treatments that offer the potential for best-in-class efficacy and improved dosing.

Third Quarter 2024 Financial Results

- **Cash Position:** As of September 30, 2024, Apogee had cash, cash equivalents and marketable securities of $753.8 million. Apogee expects that its existing 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 third quarter of 2024 were $45.7 million, compared to $17.1 million for the third quarter of 2023. R&D expenses increased primarily due to further development of the company's APG777, APG808, APG990 and APG333 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 third quarter of 2024 were $13.0 million, compared to $7.2 million for the third 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 third quarter of 2024 was $49.0 million, compared to the net loss for the third quarter of 2023 which was $20.8 million. 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 inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, 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 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 results from its clinical trials, including data from its Phase 2 trial of APG777, Phase 1 trial of APG808 and Phase 1 trial of APG990; the anticipated timing of initiation of its clinical trials, including its Phase 1 trial of APG333 and clinical trial of the APG777 and APG990 combination; its plans for current and future clinical trials; and the potential clinical benefit and half-life of APG777, Apogee's other product candidates, and any other potential programs, including combination therapies; its expected timing for future pipeline updates and 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, 2023, filed with the SEC on March 5, 2024, Quarterly Report on 10-Q for the quarterly period ended June 30, 2024, filed with the SEC on August 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.

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except unit/share data)

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 118,780	$ 118,316
Marketable securities	407,269	277,143
Prepaid expenses and other current assets	8,434	2,950
Total current assets	534,483	398,409

Long-term marketable securities	227,746	—
Property and equipment, net	1,417	377
Right-of-use asset, net	12,126	2,217
Other non-current assets	514	401
Total assets	$ 776,286	$ 401,404
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,216	$ 2,143
Lease liability	2,867	1,101
Accrued expenses	27,528	17,314
Total current liabilities	32,611	20,558
Long-term liabilities:		
Lease liability, net of current	9,273	933
Total liabilities	41,884	21,491
Stockholders' equity:		
Common Stock; $0.00001 par value, 400,000,000 authorized, 58,509,583 issued and 56,899,295 outstanding as of September 30, 2024; 400,000,000 authorized, 50,655,671 issued and 48,338,769 outstanding as of December 31, 2023	1	—
Additional paid-in capital	969,829	503,354
Accumulated other comprehensive income	3,270	329
Accumulated deficit	(238,698)	(123,770)
Total stockholders' equity	734,402	379,913
Total liabilities and stockholders' equity	$ 776,286	$ 401,404

APOGEE THERAPEUTICS, INC.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 45,714	$ 17,069	$ 107,636	$ 39,470
General and administrative	12,972	7,236	33,353	16,378
Total operating expenses	58,686	24,305	140,989	55,848
Loss from operations	(58,686)	(24,305)	(140,989)	(55,848)
Other income, net:				
Interest income, net	9,668	3,465	26,061	3,598
Total other income, net	9,668	3,465	26,061	3,598
Net loss	$ (49,018)	$ (20,840)	$ (114,928)	$ (52,250)

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