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

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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 and WALTHAM, Mass., March 05, 2024 (GLOBE NEWSWIRE) -- 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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