Apogee Highlights Corporate Progress and Reports Third Quarter 2023 Financial Results

November 13, 2023

Phase 1 clinical trial of APG777, a fully optimized, subcutaneous, extended half-life anti-IL-13 antibody, initiated ahead of schedule with initial PK and safety data from healthy volunteers expected mid-2024; on track to begin Phase 2 in moderate-to-severe atopic dermatitis in 2024

Announcing our finalized nomination of development candidate for APG808, a potentially best-in-class, femtomolar affinity, subcutaneous extended half-life antibody targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases in 4Q 2023

Well-capitalized with $422.9 million in cash following upsized IPO supporting operating runway into 4Q 2026

SAN FRANCISCO and WALTHAM, Mass., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing differentiated biologics for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other inflammatory and immunology (I&I) indications, today provided business updates and reported third quarter 2023 financial results.

“I am proud of our team’s execution during the third quarter and 2023 overall. We continue to deliver against our operating plan, advancing our lead program, APG777 for AD, into a first-in-human healthy volunteer study ahead of schedule while progressing our portfolio of potentially best-in-class biologics designed to significantly improve therapeutic options for patients across the largest markets in I&I”, said Michael Henderson, M.D., Chief Executive Officer of Apogee. “We expect to report initial PK and safety data from the Phase 1 trial for APG777 in mid-2024, a potentially key de-risking milestone, which we believe could demonstrate our potential benefit relative to the current standard of care, including optimized exposures, low variability, and extended half-life. Alongside the advancements in APG777, we are excited to announce the selection of a development candidate for our second program, APG808, and remain on track to enter the clinic in healthy volunteers in 2024 followed by a Phase 2 trial in COPD.

Pipeline Highlights and Upcoming Milestones

- **Dosing underway in Phase 1 trial of APG777:** 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. The Phase 1 trial is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics (PK) of single-ascending and multiple-ascending doses of APG777. Apogee initiated dosing of healthy volunteers ahead of schedule in August 2023. The Phase 1 clinical trial objectives are to:
  - Establish safety and PK;
  - Set Phase 2 induction regimen to achieve at least equivalent exposures as lebrikizumab, a first-generation IL-13 antibody; and
  - Support testing of maintenance dosing regimens of every 2 or 3 months while maintaining the minimal concentration of APG777 at a similar level to lebrikizumab

Apogee expects initial safety and PK data from the Phase 1 trial in mid-2024, a potentially key de-risking milestone given APG777 is targeting a validated mechanism. The goal of the Phase 1 trial is to support potential dosing every 2 to 3 months compared to the current standard of care of every 2 to 4 weeks. Apogee believes this potential for significant differentiation compared to leading therapies may contribute to a best-in-class profile for APG777. Pending positive PK and safety data, the company plans to advance into a randomized, double-blind, placebo-controlled, 16-week Phase 2 proof-of-concept trial in moderate-to-severe patients with AD in 2024 with data expected in the second half of 2025.

- **Finalized nomination of APG808 development candidate in 4Q 2023:** APG808 is an SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding femtomolar affinity for IL-4Rα as 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). Additionally, in Apogee’s head-to-head studies of APG808 and DUPIXENT in non-human primates, APG808 showed a significantly longer half-life than DUPIXENT. In these preclinical studies, APG808’s half-life was up to 26 days, as compared to 12 days for DUPIXENT. Based on these preclinical studies, we believe that the longer half-life could support dosing either every 6 weeks or every 2 months in the clinic, which, if future clinical trials are successful, would represent a significant improvement compared to DUPIXENT which is currently being investigated with every 2-week dosing in COPD. APG808 remains on track to enter the clinic in healthy volunteers in 2024 followed by a Phase 2 trial in COPD (pending data from the Phase 1 trial and following the submission of an IND to support the Phase 2 trial).

Recent Corporate Highlights

- **Completed $345 million upsized Initial Public Offering (IPO)**: In July, the company completed its upsized IPO and sold 20,297,500 shares of common stock, which included the full exercise of the underwriters' option to purchase additional shares at a price to the public of $17.00 per share. The aggregate gross proceeds to Apogee from the offering before deducting underwriting discounts and commissions and other offering expenses were approximately $345 million.

- **Presented preclinical data for APG777:** In October, at the 2023 European Academy of Dermatology and Venereology (EADV) Congress held in Berlin, Germany, Apogee presented preclinical data that highlighted the potential advantages of APG777 over current therapeutic agents targeting IL-13, including half-life.

- **Expanded board of directors and leadership team:** In August, healthcare veteran and former Chairman, President and CEO of Prometheus Biosciences, Mark C. McKenna, was appointed Chairman of the Apogee board of directors. Matt Batters also joined Apogee in August as General Counsel, a role he most recently served in at Arvinas, Inc.

Upcoming Investor Events

Apogee plans to participate in the following upcoming events:

- Stifel 2023 Healthcare Conference, November 14, New York, NY
- Jefferies London Healthcare Conference, November 15, London, UK
- Evercore ISI 6th Annual HealthCONx Conference, November 28, Miami, FL

Third Quarter Financial Results

- **Cash Position**: As of September 30, 2023, Apogee had a total cash balance of $422.9 million. Apogee expects that its existing cash will enable it to fund its current operating expenses and capital expenditure requirements into the fourth quarter of 2026.
- **Research & Development (R&D) Expenses:** R&D expenses for the third quarter of 2023 were $17.1 million, compared to $9.9 million for the third quarter of 2022. R&D expenses increased primarily due to further development of the company's APG777 and APG808 programs and advancement of its pipeline, as well as increases in personnel costs, including share-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 2023 were $7.2 million, compared to $0.6 million for the third quarter of 2022. G&A expenses increased primarily due to increases in personnel costs, including share-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 2023 was $20.8 million, compared to the net loss for the third quarter of 2022 which was $19.7 million.

About Apogee

Apogee Therapeutics is a clinical-stage biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) 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.

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, our expectations regarding plans for our current and future product candidates and programs, plans for our current and future clinical trials, plans for clinical trial design, the anticipated timing of the initiation of and results from our clinical trials, potential clinical benefit and half-life of APG777, APG808 and any other potential programs, and expectations regarding the time period over which our capital resources will be sufficient to fund our 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 our preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of our 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 our Quarterly Report of 10-Q for the quarterly period

ended June 30, 2023, filed with the SEC on August 28, 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.

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

	SEPTEMBER 30, 2023	DECEMBER 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 188,269	$ 151,890
Marketable securities	234,585	-
Prepaid expenses and other current assets	3,567	165
Total current assets	426,421	152,055
Total assets	$ 426,421	$ 152,055
Liabilities, preferred units and stockholders' equity/members' deficit		
Current liabilities:		
Accounts payable	$ 1,208	$ 418
Accrued expenses	15,970	9,562
Total current liabilities	17,178	9,980
Total liabilities	17,178	9,980
Commitments and contingencies		
Series A Preferred Units; no units authorized, issued and outstanding at September 30, 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 September 30, 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 September 30, 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 September 30, 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 September 30, 2023; No shares authorized, issued and outstanding at December 31, 2022	-	-
Common Stock; 400,000,000 authorized, $0.00001 par value, 50,674,296 issued and 48,017,621 outstanding as of September 30, 2023; No shares authorized, issued and outstanding at December 31, 2022	-	-
Additional paid-in capital	501,143	-
Accumulated other comprehensive income	135	-
Accumulated deficit	(92,035)	(39,785)
Total stockholders' equity/members' deficit	409,243	(35,392)
Total liabilities, preferred units and stockholders' equity/members' deficit	$ 426,421	$ 152,055

APOGEE THERAPEUTICS, INC.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO SEPTEMBER 30, 2022
	2023	2022	2023	
Operating expenses:				
Research and development	$ 17,069	$ 9,885	$ 39,470	$ 15,578
General and administrative	7,236	622	16,378	1,050
Total operating expenses	24,305	10,507	55,848	16,628
Loss from operations	(24,305)	(10,507)	(55,848)	(16,628)
Other income (expense), net:				
Interest income	3,465	—	3,598	—
Other financing expense	—	(9,150)	—	(9,150)
Total other income (expense), net	3,465	(9,150)	3,598	(9,150)
Net loss	$ (20,840)	$ (19,657)	$ (52,250)	$ (25,778)

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