Apogee Highlights Corporate Progress and Reports Second Quarter 2023 Financial Results

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$345 million in gross proceeds raised in upsized IPO, providing a projected operating runway into 4Q 2026

Phase 1 clinical trial initiated and first participant dosed ahead of schedule for lead product candidate, APG777, a fully optimized and half-life extended anti-IL-13 antibody for the treatment of atopic dermatitis

Leadership further strengthened with appointments of industry leaders to its board of directors and executive team

SAN FRANCISCO and WALTHAM, Mass., Aug. 28, 2023 (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) and other inflammatory and immunology (I&I) indications, today provided a review of its pipeline of potentially best-in-class monoclonal antibody (mAb) therapies for I&I diseases, along with key anticipated milestones and recent business progress. In addition, Apogee reported second quarter 2023 financial results and provided guidance on its projected operating runway.

"We have achieved remarkable growth and progress across all aspects of Apogee's business in 2023 to date, marked by the important milestones of transitioning to *both* a publicly traded and clinical-stage company," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "In the last year we have made noteworthy progress in our mission to develop therapeutic options for patients by advancing novel, potentially best in class antibodies that we believe may significantly improve upon standard of care. Our broad pipeline has the potential to overcome limitations of existing therapies for AD, asthma and COPD. And we have capitalized the company with an upsized IPO consisting of new and existing top tier investors that provides sufficient funding to support our operations through multiple clinical catalysts for our lead programs. We have attracted an incredibly talented and passionate team of industry leaders and experts across our board of directors, R&D and business operations. This is an exciting time for Apogee, and we are confident in our ability to deliver value from our potentially best-in-class therapeutic candidates to benefit patients living with I&I diseases."

Pipeline Highlights and Upcoming Milestones

- **Enrollment advancing in Phase 1 trial of APG777, with initial data expected mid-2024:** In August 2023, Apogee announced initiation of dosing of healthy volunteers for APG777, 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 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 expects initial safety and PK data from the Phase 1 trial in mid-2024, a potentially key de-risking event given APG777 is targeting a validated mechanism and has the potential to show significant differentiation compared to leading therapies. Pending positive PK and safety data, the company plans to advance into a randomized, placebo-controlled, 16-week Phase 2 proof-of-concept trial in moderate-to-severe patients with AD in 2024.

- **APG808 development candidate selection expected in 4Q 2023*:*** APG808 is an SQ extended half-life mAb program targeting IL-4Rα for the treatment of COPD. In head-to-head preclinical assays, Apogee's lead candidates have demonstrated equivalent or better potency in the inhibition of IL-4Rα signaling to the current standard-of-care.

- **APG990 program progressing as a differentiated OX40L-targeted opportunity:** APG990 is an earlier-stage SQ extended half-life mAb program designed to target OX40L, which occurs further upstream in the inflammatory pathway than IL-13 or IL-4Rα, which may lead to an expanded effect on the inflammatory cascade. Targeting OX40L represents another potential treatment approach for AD, including for patients who do not benefit from currently available therapies. Apogee expects to select a development candidate for its APG990 program in 2024.

- **APG222 program advancing with a dual mechanism targeting both IL-13 and OX40L:** APG222 is one or more SQ extended half-life mAbs targeting both IL-13 and OX40L, for the potential treatment of AD and other I&I indications. By blocking OX40L and IL-13, APG222

could simultaneously decrease OX40L signaling, helping to rebalance the immune system and decrease immune cell differentiation and cytokine release, and further reduce IL-13, resulting in even less immune signaling. This approach has the potential to prevent certain disease-related signs and symptoms that are driven by IL-13 signaling and the downstream inflammatory cascade.

- **Multiple pipeline expansion opportunities, including through Paragon collaboration:** In addition to each program's initial indication, Apogee's programs have the potential to expand into a range of I&I diseases. The company has identified asthma as a leading expansion opportunity for APG777 given the significant overlap with AD and the unmet need. In addition, under a strategic collaboration agreement with Paragon Therapeutics, Inc., Apogee plans to select and evaluate additional targets that have the potential to overcome the limitations of existing therapies by engineering best-in-class antibodies.

Recent Corporate Highlights

- **Appointed Mark C. McKenna as Chairman of the Board:** In August, Apogee expanded its board with the appointment of Mark C. McKenna, former Chairman, President and CEO of Prometheus Biosciences, Inc. which was acquired by Merck & Co., Inc. in June 2023 for approximately $10.8 billion, representing the largest pre-Phase 3 biopharma acquisition to date. Mr. McKenna's knowledge and successful track record in the I&I space as well as his significant development, commercial and executive management experience contributed to the Apogee board of directors' selection decision.

- **Designated Matt Batters as General Counsel**: Also in August, Matt Batters was appointed as General Counsel. He was previously General Counsel at Arvinas, Inc., a biotech focused on oncology and neurological diseases where he built its legal team as it moved from a private, preclinical company to a public company, led the alliance management team in supporting Arvinas's strategic collaborations, and, before becoming its General Counsel, also led its business development activities. Previously, Mr. Batters was a Senior Director on the legal team at Alexion Pharmaceuticals (now part of AstraZeneca) where he supported the business development function, and was responsible for structuring and negotiating Alexion's licensing, collaborations and M&A activities. Prior to Alexion, Mr. Batters was a corporate associate at DLA Piper and Skadden, Arps, Slate, Meagher & Flom, where he advised pharmaceutical and biotechnology clients on global corporate governance, capital raising and securities matters, as well as complex licenses, collaborations, and M&A transactions.

- **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 p **ri**ce 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.

- **Strengthened team with Board of Directors and Management Appointments:** In June, Apogee further strengthened its leadership team with the appointments of Jennifer Fox and William "BJ" Jones, seasoned financial and commercial executives, respectively, to its board. In addition, Rebecca Dabora, Ph.D., an expert in chemistry, manufacturing and controls (CMC), was appointed Chief Technical Officer.

Second Quarter Financial Results

- **Cash Position**: As of June 30, 2023, Apogee had a cash balance of $125.1 million. We expect that the Company's existing cash, together with the gross proceeds from the upsized IPO of approximately $345 million 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 second quarter of 2023 were $13.9 million, compared to $1.4 million for the second quarter of 2022. R&D expenses increased primarily due to APG777 and APG808 program advancements and increases in personnel costs, including share-based compensation expense associated with the growth of R&D team.

- **General and Administrative (G&A) Expenses:** G&A expenses for the second quarter of 2023 were $4.9 million, compared to $0.4 million for the second quarter of 2022. The increase of $4.5 million was primarily attributable to the increase in personnel costs associated with increased headcount and legal and other professional services conducted to support the growth of the business.

- **Net Loss:** Net loss for the second quarter of 2023 was $18.9 million, compared to the net loss for the second quarter of 2022 which was $1.8 million.

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) 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 properties, including half-life extension. 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, 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, APG990, APG222, and any other potential programs, potential additional indications for APG777, the anticipated timing for selection of development candidates and our other 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 Registration Statement on Form S-1, as amended, declared effective by the SEC on July 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, LLC

CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands)

	JUNE 30, 2023	DECEMBER 31, 2022
Assets		
Current assets:		
Cash	$ 125,069	$ 151,890

Prepaid expenses and other current assets	5,598	165
Total current assets	130,667	152,055
Total assets	$ 130,667	$ 152,055
Liabilities, preferred units and members' deficit		
Current liabilities:		
Accounts payable	$ 11,148	$ 418
Accrued expenses	6,467	9,562
Total current liabilities	17,615	9,980
Total liabilities	17,615	9,980
Commitments and contingencies		
Series A Preferred Units; 20,000,000 units authorized, issued and outstanding as of June 30, 2023 and December 31, 2022; liquidation of $20,000 value as of June 30, 2023 and December 31, 2022	28,971	28,971
Series B Preferred Units; 45,089,212 units authorized, issued and outstanding as of June 30, 2023 and December 31, 2022; liquidation of $149,000 value as of June 30, 2023 and December 31, 2022	148,496	148,496
Members' deficit:		
Common Units; 5,000,000 units authorized, issued and outstanding as June 30, 2023 and December 31, 2022	2,251	2,251
Incentive Units; 16,537,557 units authorized, 14,270,275 issued and 2,481,543 outstanding as of June 30, 2023; 12,412,473 units authorized, 9,648,374 issued and 1,625,086 outstanding as of December 31, 2022	4,529	2,142
Accumulated deficit	(71,195)	(39,785)
Total members' deficit	(64,415)	(35,392)
Total liabilities, preferred units and members' deficit	$ 130,667	$ 152,055

APOGEE THERAPEUTICS, LLC

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO JUNE 30,
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,946	$ 1,448	$ 22,401	$ 5,693
General and administrative	4,939	368	9,142	428
Total operating expenses	18,885	1,816	31,543	6,121
Loss from operations	(18,885)	(1,816)	(31,543)	(6,121)
Other income (expense), net:				
Interest income	—	—	133	—
Total other income (expense), net	—	—	133	—
Net loss and comprehensive loss	$ (18,885)	$ (1,816)	$ (31,410)	$ (6,121)

Investor Contacts:

Noel Kurdi
VP, Investor Relations
Apogee Therapeutics
Noel.kurdi@apogeetherapeutics.com

Alex Straus
THRUST Strategic Communications
alex@thrustsc.com

Media Contact:

Dan Budwick

1AB Media
dan@1abmedia.com