Aardvark Therapeutics Reports Second Quarter 2025 Financial Results and Provides Pipeline and Business Updates

August 13, 2025

- *Compelling new ARD-201 preclinical data informs optimized Phase 2 clinical development strategy of obesity programs: Phase 2 POWER trial of oral ARD-201 to focus on weight rebound in patients discontinuing GLP-1RA therapy, while Phase 2 STRENGTH trial to focus on durable weight loss as a monotherapy and in combination with GLP-1RA.*
- *Anticipated expansion of Phase 3 HERO trial of ARD-101 for the treatment of hyperphagia associated with Prader-Willi Syndrome (PWS) to include pediatric population younger than 13 years of age.*
- *$141.8 million in cash, cash equivalents, and short-term investments supports projected operations into 2027.*

SAN DIEGO, Aug. 13, 2025 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark) (Nasdaq: AARD), a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases, today reported financial results for the second quarter ended June 30, 2025, and provided pipeline and business updates.

“Aardvark has made significant progress across our pipeline, and we are well-positioned to unlock the full potential of ARD-101 and ARD-201 across multiple studies in the year ahead," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “Expansion of the Phase 3 HERO trial to include younger patients below the age of 13 would allow us to reach a larger segment of the PWS patient population through our registration label at launch and serve more patients in need. In addition, recent preclinical data from our ARD-201 obesity program strengthens our conviction in targeting hunger signaling pathways as a distinct and complementary approach to glucagon-like peptide-1 receptor agonist (GLP-1RA) therapies, and we’re looking forward to further exploring the promising therapeutic profile of ARD-201 in the Phase 2 POWER and STRENGTH trials.”

Clinical Program Updates

ARD-101 for PWS
With the support from the PWS community, combined with historical data showing that younger patients are more likely to benefit from early intervention, Aardvark intends to expand the Phase 3 HERO trial of ARD-101 for the treatment of hyperphagia associated with PWS to include patients under the age of 13.

ARD-201 for Obesity
Preclinical data announced on August 12, 2025 demonstrated that investigational oral obesity therapy ARD-201 not only significantly reduced body weight, but also helped prevent weight regain (weight rebound) after discontinuation of GLP-1RA. Driven by these new preclinical insights, Aardvark is advancing ARD-201 in two Phase 2 trials, the POWER and STRENGTH trials, in place of the previously planned EMPOWER trial.

Updated Milestones

- Topline data from the Phase 3 HERO trial evaluating ARD-101 for the treatment of hyperphagia associated with PWS is expected in the third quarter of 2026.
- Initiation of the Phase 2 POWER trial evaluating ARD-201’s potential to prevent weight regain in subjects who discontinue GLP-1RA therapy after achieving substantial prior weight loss (~15%) is expected in the second half of 2025.
- Initiation of the Phase 2 STRENGTH trial evaluating placebo-adjusted weight loss and the additive effects of ARD-201 combined with GLP-1RA therapy is expected in the first half of 2026.
- Initiation of the Phase 2 HONOR trial evaluating ARD-101 for the treatment of hyperphagia associated with acquired hypothalamic obesity is expected in the second half of 2025 with anticipated topline data readout in the second half of 2026.

Summary of Business Highlights

- In May 2025, Aardvark bolstered its leadership team with strategic hires across scientific, commercial, regulatory and legal functions with the appointments of Timothy Kieffer, Ph.D., as Chief Scientific Officer; Danny Villeneuve as Chief Commercial Officer; Terrie Kellmeyer, Ph.D., as Senior Vice President, Regulatory Affairs; and Christian Zapf, J.D., as General Counsel.
- In June 2025, Aardvark presented previously disclosed data from its Phase 2 trial of ARD-101 in PWS in a poster and a five-minute “lightning” oral presentation at the 2025 United in Hope Conference. In addition, Aardvark’s Chief Medical Officer, Manasi Jaiman, M.D., participated in a panel with clinicians to discuss the details of the company’s ongoing Phase 3 HERO trial.

Select Second Quarter 2025 Financial Highlights

- **Cash Position:** As of June 30, 2025, Aardvark had cash, cash equivalents, and short-term investments of $141.8 million. Based on current operating plans, Aardvark believes that its existing cash, cash equivalents, and short-term investments will be sufficient to fund projected operations into 2027.
- **R&D Expenses:** Research and development expenses were $13.1 million and $4.0 million for the quarter ended June 30, 2025, and 2024, respectively. The $9.1 million increase for the quarter ended June 30, 2025, resulted from increased development costs primarily related to ARD-101 and an increase in personnel-related expenses.
- **G&A Expenses:** General and administrative expenses were $2.7 million and $2.0 million for the quarter ended June 30, 2025, and 2024, respectively. The $0.7 million increase for the quarter ended June 30, 2025, primarily resulted from increases in professional fees, facilities and other and personnel-related costs, which were partially related to commencing operations as a public company.
- **Net loss:** Net loss was $14.4 million and $5.4 million for the quarter ended June 30, 2025, and 2024, respectively, primarily due to increased research and development and general and administrative expenses.

About Aardvark Therapeutics, Inc.
Aardvark is a clinical-stage biopharmaceutical company developing novel, small-molecule therapeutics designed to suppress hunger for the treatment of PWS and metabolic diseases. Recognizing hunger (the discomfort from not having eaten recently) is a distinct neural signaling pathway separate from appetite (the reward-seeking, desirability of food). Our programs explore therapeutic applications in hunger-associated indications and potential complementary uses with anti-appetite therapies. Our lead compound, oral ARD-101, is in Phase 3 clinical development for the treatment of hyperphagia associated with PWS, a rare disease characterized by insatiable hunger. ARD-101 is also being studied in hypothalamic obesity. Additionally, Aardvark is developing ARD-201, a fixed-dose combination of ARD-101 with a DPP-4 inhibitor, and conducting two separate trials, with a goal of addressing some of the limitations of currently marketed GLP-1 therapies for the treatment of obesity and obesity-related conditions. For more information, visit aardvarktherapeutics.com.

Forward-Looking Statements
Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements.” These statements include, but are not limited to, statements concerning: Aardvark’s future results of operations and financial position, business strategy, product candidates, ongoing clinical trials, planned clinical trials, expected timing for data readouts and reporting topline results, anticipated cash runway, likelihood of success, as well as plans and objectives of management for future operations. Words including, without limitation, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “promising,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Forward-looking statements in this press release include statements regarding ARD-101, including the anticipated expansion of the Phase 3 HERO trial for the treatment of hyperphagia associated PWS to include pediatric population younger than 13 years of age and the expected timeline for receiving topline data from the Phase 3 HERO trial; ARD-201’s potential, including its potential as a monotherapy and in combination with GLP-1RA and its promising therapeutic profile; and the trial design for the POWER and STRENGTH trials and the expected timing for commencing such trials. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to potential delays in the commencement, enrollment and completion of clinical trials; the risk that we may use our capital resources sooner than expected and that they may be insufficient to allow us to achieve our anticipated milestones; risks related to our dependence on third parties for manufacturing, shipping and production of drug product for use in clinical and preclinical trials; the risk of unfavorable clinical trial results; the risk that results from earlier clinical trials and preclinical studies may not necessarily be predictive of future results; and other factors discussed in the “Risk Factors” section of Aardvark’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 to be filed with the Securities and Exchange Commission on or about the date hereof. When evaluating Aardvark’s business and prospects, careful consideration should be given to these risks and uncertainties. Any forward-looking statements contained in this press release are based on the current expectations of Aardvark’s management team and speak only as of the date hereof, and Aardvark specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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Aardvark Therapeutics, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended June 30,	Six Months Ended June 30,

	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 13,145	$ 4,029	$ 20,900	$ 5,236
General and administrative	2,703	2,030	5,418	2,891
Credit loss—related party accounts receivable	—	14	—	117
Total operating expenses	15,848	6,073	26,318	8,244
Loss from operations	(15,848)	(6,073)	(26,318)	(8,244)
Total other income (expense), net	1,481	624	2,641	617
Net loss	$ (14,367)	$ (5,449)	$ (23,677)	$ (7,627)
Net loss per share of common stock, basic and diluted	$ (0.66)	$ (1.37)	$ (1.36)	$ (1.92)
Weighted-average shares used in net loss per share calculation	21,690,275	3,967,984	17,465,965	3,967,658

Aardvark Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 25,998	$ 61,641
Short-term investments	115,822	12,022
Prepaid expenses and other current assets	2,948	474
Total current assets	144,768	74,137
Operating lease right-of-use asset	522	735
Other assets	2,185	2,635
Total assets	$ 147,475	$ 77,507
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,056	$ 2,298
Accrued liabilities	4,837	2,291
Operating lease liability, current portion	417	338
Total current liabilities	10,310	4,927
Operating lease liability, net of current portion	228	441
Other long-term liabilities	12	26
Total liabilities	10,550	5,394
Commitments and contingencies		
Convertible preferred stock	—	126,756
Stockholders' equity (deficit):		
Common stock	—	—
Additional paid-in-capital	218,932	3,684
Accumulated other comprehensive income	(3)	—
Accumulated deficit	(82,004)	(58,327)
Total stockholders' equity (deficit)	136,925	(54,643)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 147,475	$ 77,507