Aardvark Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Updates

March 23, 2026

Voluntary pause of the Phase 3 HERO and OLE trials evaluating ARD-101 for the treatment of hyperphagia in individuals with Prader-Willi Syndrome, further guidance on the program expected in Q2 2026

ARD-201 obesity program, including POWER and STRENGTH trials, on voluntary pause pending next steps with ARD-101; further guidance on the program expected in Q2 2026

Clinical and preclinical data from ARD-101 program published in Molecular Metabolism

$110.0 million in cash, cash equivalents and short-term investments as of December 31, 2025, supports projected operations into the second quarter of 2027

SAN DIEGO, March 23, 2026 (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 fourth quarter and full year ended December 31, 2025, and provided pipeline and business updates.

“Patient safety will always be our highest priority, and we are actively engaging with the FDA with urgency to determine the best path forward for our programs. As we evaluate next steps, we want to thank the Prader-Willi Syndrome community for its collaboration throughout this process. The community’s strength and tenacity continue to inspire our work,” said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “With positive clinical data, an encouraging safety profile from previous trials and our recently developed understanding of the clear blood plasma exposure-response relationship with reversible cardiac QRS prolongation, we have confidence in ARD-101. We strongly believe that ARD-101 retains its potential as a differentiated therapeutic option for hyperphagia in individuals living with PWS. We hope to resume the PWS development program in a timely manner and expect to provide further guidance on each of our programs in the second quarter of 2026.”

Pipeline Updates

ARD-101 for Prader-Willi Syndrome (PWS)

- In February 2026, the company announced a voluntary pause in enrollment and dosing in the Phase 3 Hunger Elimination or Reduction Objective (HERO) and open-label extension (OLE) trials evaluating ARD-101 for the treatment of hyperphagia in individuals with PWS following unexpected reversible cardiac observations in a separate healthy volunteer trial (non-PWS individuals). The healthy volunteer trial was conducted as a routine additional cardiac safety study to satisfy anticipated requirements for a future New Drug Application (NDA) for ARD-101. No cardiac signals were observed in the prior Phase 1 or Phase 2 clinical trials, and preclinical studies did not predict the expectation of cardiac safety liabilities.
    - Two of eight participants experienced increases in QRS duration greater than 25% from baseline, and one additional participant had a QRS increase of less than 25% from baseline. A finding of QRS duration greater than 25% of baseline was considered significant per protocol. These participants in the healthy volunteer study were dosed at 1,600 mg twice daily without prior dose escalation, representing twice the target dose used in the HERO study (800 mg twice daily). The dosing in this healthy volunteer study is also in contrast to the dose-escalation approach used in the HERO trial, where patients received ARD-101 in a stepwise dose escalation: first at 200 mg twice daily for one week, then 400 mg twice daily for one week, then 800 mg twice daily for 10 weeks. All QRS increases were not reported as serious adverse events, were not accompanied by serious cardiac symptoms, and were reversible upon drug discontinuation and without medical intervention.
    - The company subsequently conducted a trial with a follow-on cohort in healthy volunteers at a dose of 800 mg twice daily for up to one week, also without prior dose escalation, in which one of 23 participants experienced a transient increase in QRS duration of less than 25% from baseline, and one additional participant experienced an increase in QRS duration of greater than 25% from baseline. Again, these observations were not reported as serious adverse events, were not accompanied by serious cardiac symptoms, and were reversible with drug discontinuation without medical intervention.
    - Preliminary analysis of data from this healthy volunteer study indicates a clear exposure-response relationship where higher plasma concentrations are associated with an increased risk of QRS prolongation. For example, in exposure-response modeling, a 200 mg twice daily dose yields plasma concentrations substantially below the threshold where QRS effects are observed.
- Aardvark is conducting a comprehensive review of the data and is working closely with the U.S. Food and Drug Administration (FDA) to determine next steps. The company expects to provide further guidance in the second quarter of 2026.

Clinical and Preclinical Data From ARD-101 Program Published in *Molecular Metabolism*

- In March 2026, clinical and preclinical data for the ARD-101 program were published in the peer-reviewed journal *Molecular Metabolism*. The publication details findings from the Phase 2 proof-of-concept obesity study demonstrating that ARD-101 significantly reduced self-reported hunger on the Control of Eating Questionnaire (CoEQ) at Day 28 versus placebo, with directionally favorable improvements observed across additional CoEQ domains. In adults with obesity treated with ARD-101 (200 mg twice daily) for 28 days, CoEQ hunger decreased by 1.63 points versus 0.65 points with placebo.
- Also included in the published manuscript is a separate double-blind study in fasted healthy participants, where ARD-101 increased post-dose peptide YY (PYY) and glucagon-like peptide-1 (GLP-1), with trends toward increased cholecystokinin (CCK) and reduced ghrelin versus placebo – supporting engagement of gut–brain pathways relevant to hunger and hyperphagia.
- Together, these effects on clinical hunger signals and gut-hormone findings, combined with data from preclinical models of metabolic dysfunction, support Aardvark's continued evaluation of ARD-101 as a potential therapy for pathological hunger and hyperphagia, including in PWS.
- The full online publication can be accessed here.

ARD-201 for Obesity

- While Aardvark conducts a comprehensive review of the data and is actively engaging with the FDA, the company has also voluntarily paused the ARD-201 trials.
- This voluntary pause includes the Phase 2 Prevention of Weight Regain (POWER) trial evaluating a fixed dose combination of ARD-101 and a dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of obesity in the prevention of weight regain among patients who have successfully lost approximately 15% of body weight on GLP-1RA therapy, and the Phase 2 Sitagliptin and TAS2R for Weight Reduction with Exercise, Nutrition, and GLP-1RA Trial and Hunger Assessment (STRENGTH) trial to evaluate placebo-adjusted weight loss and the additive effects of ARD-201 combined with GLP-1RA.
- Aardvark expects to provide further guidance on the program in the second quarter of 2026.

Fourth Quarter and Full Year 2025 Financial Highlights

- **Cash Position:** As of December 31, 2025, Aardvark had cash, cash equivalents and short-term investments of $110.0 million, compared to $73.7 million as of December 31, 2024. 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 the second quarter of 2027.
- **Research & Development (R&D):** R&D expenses for the fourth quarter of 2025 were $14.3 million, compared to $8.1 million for the fourth quarter of 2024. R&D expenses were $48.9 million for the year ended December 31, 2025, compared to $17.4 million for the year ended December 31, 2024. The $31.6 million increase for the year ended December 31, 2025 as compared to the year ended December 31, 2024 resulted primarily from an increase of $23.4 million for external expenses incurred primarily related to the development of ARD-101 and a $7.7 million increase in personnel-related costs.
- **General & Administrative (G&A):** G&A expenses for the fourth quarter of 2025 were $4.4 million, compared to $1.4 million for the fourth quarter of 2024. G&A expenses were $13.8 million for the year ended December 31, 2025, compared to $5.3 million for the year ended December 31, 2024. The $8.5 million increase for the year ended December 31, 2025 as compared to the year ended December 31, 2024 included additional public company operating costs and resulted primarily from a $4.5 million increase in personnel-related costs, a $2.4 million increase in legal, accounting and other professional services costs, a $0.7 million increase in facilities and other costs, and a $0.6 million increase in insurance costs.
- **Net loss:** Aardvark reported a net loss of $17.6 million for the fourth quarter of 2025, compared to a net loss of $8.8 million for the fourth quarter of 2024. Aardvark reported a net loss of $57.6 million for the year ended December 31, 2025, compared to a net loss of $20.6 million for the year ended December 31, 2024.

About Aardvark Therapeutics, Inc.
Aardvark is a clinical-stage biopharmaceutical company developing novel, small-molecule therapeutics designed to suppress hunger for the treatment of Prader-Willi Syndrome (PWS) and metabolic diseases. Hunger, which is the discomfort from not having eaten recently, is a distinct neural signaling pathway separate from appetite, the reward-seeking desire for 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. Aardvark is also developing ARD-201, a planned fixed-dose combination of ARD-101 with a DPP-4 inhibitor, with a goal of addressing some of the limitations of currently marketed GLP-1 therapies for obesity and obesity-related conditions. For more information, visit www.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 business strategy, product candidates, ongoing clinical trials, planned clinical trials, likelihood of

success, as well as plans and objectives of management for future operations. The words, without limitation, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “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 the voluntary pauses on Aardvark’s clinical trials, Aardvark’s anticipated cash runway, Aardvark’s engagement with the FDA, Aardvark’s future plans for its PWS and obesity programs and statements regarding ARD-101 and ARD-201, including the expected timeline for providing further guidance on these programs. 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, recommencement, enrollment and completion of clinical trials and any additional actions that may be required following Aardvark’s engagement with the FDA; the risk that Aardvark may use its capital resources sooner than expected and that they may be insufficient to allow Aardvark to achieve its anticipated milestones; the possibility that the past track records of Aardvark and its personnel may not be repeated or indicative of future success; risks related to its dependence on third parties for manufacturing, shipping and production of drug product for use in clinical trials and preclinical studies; 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 risks and uncertainties, including the factors described under the “Risk Factors” section of Aardvark’s Annual Report on Form 10-K for the year ended December 31, 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, unless required by law.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 14,299	$ 8,062	$ 48,936	$ 17,363
General and administrative	4,405	1,388	13,789	5,305
Credit loss—related party accounts receivable	—	—	—	117
Total operating expenses	18,704	9,450	62,725	22,785
Loss from operations	(18,704)	(9,450)	(62,725)	(22,785)
Total other income (expense), net	1,106	671	5,134	2,197
Net loss	$ (17,598)	$ (8,779)	$ (57,591)	$ (20,588)
Net loss per share of common stock, basic and diluted	$ (0.81)	$ (2.16)	$ (2.93)	$ (5.15)
Weighted-average shares used in net loss per share calculation	21,782,325	4,062,566	19,624,626	3,996,376

Aardvark Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31,	
	2025	2024
Assets		

Current assets:		
Cash and cash equivalents	$ 47,051	$ 61,641
Short-term investments	62,976	12,022
Prepaid expenses and other current assets	1,859	474
Total current assets	111,886	74,137
Operating lease right-of-use asset	355	735
Other assets	4,940	2,635
Total assets	$ 117,181	$ 77,507
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,072	$ 2,298
Accrued liabilities	8,035	2,291
Operating lease liability, current portion	441	338
Total current liabilities	10,548	4,927
Operating lease liability, net of current portion	—	441
Other long-term liabilities	—	26
Total liabilities	10,548	5,394
Commitments and contingencies		
Convertible preferred stock	—	126,756
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	—	—
Additional paid-in-capital	222,470	3,684
Accumulated other comprehensive income	81	—
Accumulated deficit	(115,918)	(58,327)
Total stockholders' equity (deficit)	106,633	(54,643)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 117,181	$ 77,507