Aardvark Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Updates

November 13, 2026

FDA lifted clinical hold on ARD-101 for the treatment of hyperphagia in Prader-Willi Syndrome (PWS)

Meeting with the FDA scheduled for the first quarter of 2027 to discuss the Company's proposed clinical development plan for ARD-101; Company expects to resume PWS clinical activities in 2027

Exploratory data from the terminated HERO and OLE trials showed numerically greater HQ-CT score reductions with ARD-101 than placebo, with a generally well-tolerated safety profile

$60.3 million in cash, cash equivalents and short-term investments as of September 30, 2026, supports projected operations through 2027

SAN DIEGO, Nov. 13, 2026 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark or the Company) (Nasdaq: AARD), 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, today reported financial results for the third quarter ended September 30, 2026, and provided business updates.

"The lifting of the clinical hold and the FDA's agreement that we may conduct an open-label trial at 200 mg twice daily are important steps toward resuming clinical development of ARD-101 in PWS," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "We have developed a proposed clinical development plan and look forward to discussing it with the FDA. We remain committed to advancing ARD-101 for patients and families affected by PWS."

Pipeline Updates

- In October 2026, the U.S. Food and Drug Administration (FDA) lifted the clinical hold on the Company's Investigational New Drug (IND) application for ARD-101 for the treatment of hyperphagia in PWS. As required by the FDA, the Company conducted an electrocardiogram (ECG) study in healthy volunteers and an in vitro cardiac sodium channel (NaV1.5) study. No prolongation of the QRS interval or the QT interval was observed at ARD-101 doses of 200 mg or 400 mg twice daily (BID). The FDA has agreed that Aardvark may conduct an open-label trial at 200 mg BID in patients with PWS.
- In October 2026, Aardvark reported exploratory data from the terminated Phase 3 Hunger Elimination or Reduction Objective (HERO) trial and the open-label extension (OLE) trial. The HERO trial randomized 67 of the planned 90 participants before it was terminated early; as such, all efficacy data are considered exploratory, observational, inconclusive and too limited to support reliable interpretation. Highlights included:
    - Hyperphagia Questionnaire for Clinical Trials (HQ-CT) scores decreased in both treatment groups, with numerically greater reductions for ARD-101 than placebo at Weeks 2, 4, and 8. Due to early termination, evaluable participants declined from 30 (ARD-101) and 31 (placebo) at Week 2 to 11 and 13, respectively, at Week 12, limiting interpretation of the exploratory findings.
    - In the HERO intent-to-treat population with baseline HQ-CT scores of 13 or greater, the mean improvement from baseline in the clinician-rated Clinical Global Impression of Severity (CGI-S) score was numerically greater with ARD-101 than with placebo at every scheduled visit, including Week 12.
    - In the OLE cohort, participants who switched from placebo to ARD-101 had an observed average additional reduction of 6 points in HQ-CT score after four weeks of treatment. Among OLE participants who received either placebo or ARD-101 in the HERO trial, there was an average 11.8-point reduction in HQ-CT score relative to their baseline score at the start of the HERO trial. The OLE trial was open-label and did not include a control group.
    - ARD-101 was generally well tolerated, with most adverse events being mild to moderate. In the HERO trial, treatment-emergent adverse events were reported in 52% of ARD-101 participants and 50% of placebo participants, and treatment-related adverse events were reported in 15% of ARD-101 participants and 21% of placebo participants. One serious cardiac adverse event was observed in the HERO trial at 800 mg BID in a participant who was also taking pitolisant, a CYP2D6 substrate. The FDA concurred that this event was due to a drug-drug interaction with pitolisant. ARD-101 inhibits CYP2D6, the enzyme that metabolizes pitolisant. As with other approved drugs that inhibit CYP2D6, Aardvark believes this risk may be able to be managed through measures such as restricting, or adjusting the dose of, concomitant medications that are CYP2D6 substrates.
- Following the lifting of the clinical hold, Aardvark requested a meeting with the FDA, which has been scheduled for the first quarter of 2027, to discuss its proposed clinical development plan for ARD-101 in PWS. The Company intends to provide further details on the development pathway following FDA feedback. The Company expects to resume PWS clinical activities in 2027, subject to alignment with the FDA.

Corporate Update

- In October 2026, Aardvark appointed David Zhang, Ph.D., MBA, to its Board of Directors as an independent director. Dr. Zhang brings more than 25 years of experience in clinical strategy, biostatistics and regulatory submissions, including oversight of the pivotal trial design, readout and New Drug Application for CAMZYOS® (mavacamten) at MyoKardia. He currently serves as Chief Strategy Officer of Abivax S.A.

Third Quarter 2026 Financial Highlights

- **Cash Position:** As of September 30, 2026, Aardvark had cash, cash equivalents and short-term investments of $60.3 million, compared to $73.9 million as of June 30, 2026. Based on current operating plans, Aardvark believes that its existing cash, cash equivalents and short-term investments will be sufficient to fund projected operations through 2027.
- **Research & Development (R&D):** R&D expenses for the third quarter of 2026 were $15.7 million, compared to $13.7 million for the third quarter of 2025. The $1.9 million increase for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025 resulted primarily from costs associated with the FDA-required cardiac safety study of ARD-101 and higher personnel-related costs, partially offset by lower clinical trial costs following the termination of the HERO and OLE trials.
- **General & Administrative (G&A):** G&A expenses were $4.0 million for each of the third quarters of 2026 and 2025.
- **Net Loss:** Aardvark reported a net loss of $19.2 million for the third quarter of 2026, compared to $16.3 million for the third quarter of 2025.

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 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. 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, the path forward for ARD-101, including the anticipated resumption of dosing of ARD-101 in patients with PWS and anticipated doses to be used in future trials, the timing, design and outcome of the planned open-label trial, the anticipated timing of Aardvark’s meeting with the FDA, the timing for resuming clinical activities, and Aardvark’s planned engagement with the FDA regarding its Phase 3 program and the potential for any future Phase 3 trial to support a future marketing application or regulatory approval, 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 also include statements regarding Aardvark’s anticipated cash runway; Aardvark’s belief that risks related to drug-drug interactions may be able to be managed through concomitant medication restrictions or dose adjustments; the interpretation and potential implications of exploratory data from the HERO and OLE trials; the potential of ARD-101 as a treatment option for patients with PWS; and Aardvark’s future plans for its PWS program. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the FDA may not agree with Aardvark’s proposed Phase 3 program or may require additional studies; the risk that the timing of Aardvark’s meeting with the FDA may be delayed; the timing of resuming dosing and activating clinical sites; uncertainties related to potential delays in the commencement, enrollment and completion of clinical trials; the risk of additional safety findings, including risks related to cardiac safety and drug-drug interactions; limitations in interpreting data from the HERO trial and its OLE trial, which were terminated early and were not powered to assess efficacy, including the risk that exploratory, subgroup and uncontrolled analyses may not be confirmed in future 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; Aardvark’s ability to raise sufficient capital to fund its planned Phase 3 program; 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 Aardvark’s dependence on third parties for manufacturing, shipping and production of drug product for use in clinical trials and preclinical studies; risks related to competition; Aardvark’s ability to obtain, maintain and enforce intellectual property protection for ARD-101; Aardvark’s ability to retain key personnel following its June 2026 workforce reduction; general economic, market and industry conditions; and other risks and uncertainties, including the factors described under the “Risk Factors” section of Aardvark’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, 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.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 15,670	$ 13,737	$ 42,692	$ 34,637
General and administrative	4,047	3,966	14,573	9,384
Total operating expenses	19,717	17,703	57,265	44,021
Loss from operations	(19,717)	(17,703)	(57,265)	(44,021)
Total other income, net	531	1,387	2,104	4,028
Net loss	$ (19,186)	$ (16,316)	$ (55,161)	$ (39,993)
Net loss per share of common stock, basic and diluted	$ (0.88)	$ (0.75)	$ (2.52)	$ (2.12)
Weighted-average shares used in net loss per share calculation	21,886,684	21,713,858	21,849,902	18,897,489

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

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 60,335	$ 47,051
Short-term investments	13	62,976
Prepaid expenses and other current assets	3,758	1,859
Total current assets	64,106	111,886
Operating lease right-of-use asset	532	355
Other assets	162	4,940
Total assets	$ 64,800	$ 117,181
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,589	$ 2,072
Accrued liabilities	5,032	8,035
Operating lease liability, current portion	413	441
Total current liabilities	7,034	10,548
Operating lease liability, net of current portion	159	—
Total liabilities	7,193	10,548
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	—	—
Additional paid-in-capital	228,686	222,470

Accumulated other comprehensive income	—	81
Accumulated deficit	(171,079)	(115,918)
Total stockholders' equity	57,607	106,633
Total liabilities and stockholders' equity	$ 64,800	$ 117,181