Aardvark Therapeutics Reports Full Year 2024 Financial Results and Provides Business Highlights

March 31, 2025

- *Lead candidate ARD-101 demonstrated clinical activity and was generally well tolerated in a two-part Phase 2 trial in Prader-Willi Syndrome (PWS), with meaningful reductions in hyperphagia (up to a 16-point HQ-CT reduction, with an average reduction of approximately 8 points among subjects that followed trial protocol) observed during the 28-day dosing period.*
- *DEXA scans analysis from the PWS Phase 2 trial data measuring body composition indicated a trend toward decreased body fat (approximately 1.5%) and increased lean muscle (over 2%) following 28 days of ARD-101 dosing.*
- *Ongoing ARD-101 Phase 3 HERO trial to treat hyperphagia associated with PWS is expected to generate topline data in early 2026.*
- *Aardvark bolstered its cash runway through the successful completion of its Initial Public Offering (IPO) in February 2025.*

SAN DIEGO, March 31, 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 full year ended December 31, 2024, and provided business highlights.

“Appetite represents a reward-based neurological drive and hunger represents a penalty or pain avoidance neurological drive. Many approved obesity medications, including GLP-1RA agents, primarily regulate appetite, and Aardvark believes there is a significant, untapped opportunity to target anti-hunger signaling to treat metabolic rare diseases and obesity,” said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “ARD-101 is intended to address hunger by lowering the discomfort of fasting without notably decreasing the appeal of food or inducing nausea. We are pursuing certain medical conditions related to overeating or hyperphagia that may be primarily driven by hunger more than appetite, including Prader-Willi Syndrome, hypothalamic obesity, and at least some subsets of general obesity.”

Summary of Business Highlights

- Phase 2 data for the treatment of hyperphagia associated with PWS showed multiple encouraging signals. As a result, Aardvark has advanced its clinical pipeline with the initiation of the potentially pivotal Phase 3 HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial evaluating ARD-101 for hyperphagia associated with PWS.
- Achieved a successful IPO with $97.9 million in gross proceeds to support ongoing and future pipeline development.
- Strengthened executive leadership with the addition of Manasi Sinha Jaiman, M.D., M.P.H., a proven clinical strategist, as Chief Medical Officer.
- Enhanced board expertise with the appointment of Roy D. Baynes, M.D., Ph.D., and Susan E. Graf, RPh, MBA, to the Board of Directors.

Anticipated Milestones

- Initiation of the Phase 2 HONOR trial of ARD-101 for the treatment of hyperphagia associated with acquired hypothalamic obesity is expected in the second half of 2025.
- Initiation of the Phase 2 EMPOWER trial of ARD-201 for the treatment of obesity and obesity-related conditions as a fixed-dose combination of ARD-101 with a dipeptidyl peptidase-4 (DPP-4) inhibitor is expected in the second half of 2025.
- Topline data from the Phase 3 HERO trial for the treatment of hyperphagia associated with PWS is expected in early 2026.

Select Full Year 2024 Financial Highlights

- **Cash Position:** As of December 31, 2024, Aardvark had cash, cash equivalents, and short-term investments of $73.7 million, which does not include the proceeds from our IPO in February 2025. Based on current operating plans, Aardvark believes that our existing cash, cash equivalents, and short-term investments, together with the proceeds from our IPO, will be sufficient to fund projected operations into 2027.

- **R&D Expenses:** Research and development expenses were $17.4 million and $4.5 million for the year ended December 31, 2024 and 2023, respectively. The $12.9 million increase for the year ended December 31, 2024, resulted from increased development costs primarily related to ARD-101 and an increase in personnel-related expenses.

- **G&A Expenses:** G&A expenses were $5.3 million and $2.2 million for the year ended December 31, 2024, and 2023, respectively. The $3.1 million increase for the year ended December 31, 2024, primarily resulted from increases in personnel-related costs and other professional costs.

- **Net loss:** Net loss was $20.6 million and $7.2 million for the year ended December 31, 2024, and 2023, respectively.

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. Aardvark is also developing ARD-201, a 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 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. 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. 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 clinical and preclinical trials; 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 Annual Report on Form 10-K for the year ended December 31, 2024 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.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 17,363	$ 4,480
General and administrative	5,305	2,173
Credit loss—related party accounts receivable	117	762
Total operating expenses	22,785	7,415
Loss from operations	(22,785)	(7,415)
Total other income, net	2,197	207
Net loss and comprehensive net loss	$ (20,588)	$ (7,208)
Net loss per share of common stock, basic and diluted	$ (5.15)	$ (1.82)
Weighted-average shares used in net loss per share calculation	3,996,376	3,960,944

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

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 61,641	$ 9,735
Short-term investments	12,022	254
Prepaid expenses and other current assets	474	379
Total current assets	74,137	10,368
Operating lease right-of-use asset	735	155
Other assets	2,635	13
Total assets	$ 77,507	$ 10,536
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,298	$ 1,035
Accrued liabilities	2,291	235
Operating lease liability, current portion	338	112
Total current liabilities	4,927	1,382
Operating lease liability, net of current portion	441	50
Other long-term liabilities	26	2
Total liabilities	5,394	1,434
Commitments and contingencies		
Convertible preferred stock	126,756	43,904
Stockholders' deficit:		
Common stock	-	-
Additional paid-in-capital	3,684	2,937
Accumulated deficit	(58,327)	(37,739)
Total stockholders' deficit	(54,643)	(34,802)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 77,507	$ 10,536