UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2025

Aardvark Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-42513**	**82-1606367**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4370 La Jolla Village Drive, Suite 1050 **San Diego, California**	**92122**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 225-7696

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	AARD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2025, Aardvark Therapeutics, Inc. issued a press release reporting its financial results for the third quarter ended September 30, 2025, and providing pipeline and business updates. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 13, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AARDVARK THERAPEUTICS, INC.

Date: November 13, 2025

By: /s/ Tien-Li Lee, M.D.
Tien-Li Lee, M.D.
Chief Executive Officer

Exhibit 99.1

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

Aardvark has aligned with the FDA to reduce the minimum age of eligibility from 13 to 10 years old for pediatric patients in HERO, the Phase 3 trial of ARD-101 for the treatment of hyperphagia associated with Prader-Willi Syndrome (PWS)

New preclinical data presented at ObesityWeek 2025 demonstrates the potential of ARD-201 in enhanced glucose control, along with preservation of lean body mass, underscoring its opportunity in addressing key challenges in today's obesity treatment landscape

Oral ARD-201 shows potential for weight management after GLP-1RA discontinuation, supported by new promising preclinical results and ARD-101 clinical data

$126.4 million in cash, cash equivalents, and short-term investments as of September 30, 2025, supports projected operations into 2027

SAN DIEGO, CA, November 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 third quarter ended September 30, 2025, and provided pipeline and business updates.

"During ObesityWeek, we highlighted new preclinical data demonstrating the potential of ARD-201 in enhanced glucose control, along with preservation of lean mass, underscoring its opportunity in addressing key challenges in today's obesity treatment landscape. The data were met with encouraging feedback from Key Opinion Leaders who attended the meeting," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "We also presented clinical data on ARD-101 and preclinical data on ARD-201 demonstrating the potential of oral ARD-201 to attenuate weight gain, promote weight loss and help maintain weight after GLP-1RA discontinuation. We're looking forward to advancing ARD-201 into two Phase 2 trials, POWER and STRENGTH, to further evaluate its potential for individuals living with metabolic obesity."

Clinical Program Updates

ARD-101 for PWS
In October 2025, Aardvark reached alignment with the FDA on a protocol amendment to change the minimum age of eligibility to participate in the Phase 3 HERO trial of ARD-101 for the treatment of hyperphagia associated with PWS trial from 13 to 10 years of age. This change broadens the eligible population for the trial and expands the potential target market within the PWS market. In addition, during the third quarter of 2025, Aardvark commenced enrollment for the HERO Open Label Extension (OLE) trial and initiated its first clinical trial sites in Australia with a minimum age of eligibility to participate at 10 years of age. The OLE trial is available to patients completing the HERO clinical trial.

ARD-201 for Obesity

At ObesityWeek 2025, Aardvark presented preclinical data on ARD-201 and clinical data on ARD-101 supporting the continued development of ARD-201 to attenuate weight gain, promote weight loss, and help maintain weight after the discontinuation of glucagon-like peptide-1 receptor agonist (GLP-1RA) therapies. In addition, ARD-201 improved glucose tolerance and lean body mass composition. Highlights from the data presented included:

- Preclinical – ARD-201 (Validated Diet-Induced Obesity (DIO) Mouse Model):
  - Transition from high-dose tirzepatide to ARD-201 preserved lean mass
  - Transition to ARD-201 achieved glucose control comparable to staying on high-dose tirzepatide, while a combination of ARD-201 with low-dose tirzepatide further enhanced glucose clearance
  - Previously reported preclinical data demonstrated ARD-201 reduced body weight by ~19% after 30 days, which was comparable to high-dose tirzepatide
  - Previously reported preclinical data demonstrated ARD-201 achieved ~30% weight loss when combined low-dose tirzepatide
- Clinical – ARD-101 (Randomized, 28-Day, Placebo-Controlled, Phase 2A Study in Adults with Obesity):
  - ARD-101 showed signals of weight control, reduced hunger, and improved metabolic parameters, particularly among participants with elevated baseline values
  - ARD-101 was well tolerated, with no serious adverse events or treatment discontinuations, reflecting a distinct profile from the effects associated with current anti-obesity therapies

Anticipated 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
- Preliminary or interim data from the Phase 2 POWER trial is anticipated to be available in 2H 2026.

Select Third Quarter 2025 Financial Highlights

- **Cash Position:** As of September 30, 2025, Aardvark had cash, cash equivalents, and short-term investments of $126.4 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 $13.7 million and $4.1 million for the quarter ended September 30, 2025, and 2024, respectively. The $9.7 million increase for the quarter ended September 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 $4.0 million and $1.0 million for the quarter ended September 30, 2025, and 2024, respectively. The $2.9 million increase for the quarter ended September 30, 2025, primarily resulted from increases in personnel-related costs, facilities and other costs, and professional fees, which were partially related to commencing operations as a public company in February 2025.

- **Net loss:** Net loss for the quarter ending September 20, 2025, was $16.3 million compared to $4.2 million quarter ending September 20, 2024, 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 Prader-Willi Syndrome 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. Aardvark is also developing ARD-201, a planned 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 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 future results of operations and financial position, business strategy, product candidates, ongoing clinical trials, planned clinical trials, expected timing for data readouts and reporting interim, preliminary or 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 expected timeline for receiving topline data from the Phase 3 HERO trial; ARD-201’s potential, including its potential in enhanced glucose control, preservation of lean body mass, attenuation of weight gain, promotion of weight loss and maintaining weight after GLP-1RA discontinuation; and the expected timing for reporting preliminary or interim data from the Phase 2 POWER trial. 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 September 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, 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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 13,737	$ 4,065	$ 34,637	$ 9,301
General and administrative	3,966	1,026	9,384	3,917
Credit loss—related party accounts receivable	—	—	—	117
Total operating expenses	17,703	5,091	44,021	13,335
Loss from operations	(17,703)	(5,091)	(44,021)	(13,335)
Total other income (expense), net	1,387	909	4,028	1,526
Net loss	$ (16,316)	$ (4,182)	$ (39,993)	$ (11,809)
Net loss per share of common stock, basic and diluted	$ (0.75)	$ (1.05)	$ (2.12)	$ (2.97)
Weighted-average shares used in net loss per share calculation	21,713,858	3,986,997	18,897,489	3,974,152

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

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 39,285	$ 61,641
Short-term investments	87,065	12,022
Prepaid expenses and other current assets	2,857	474
Total current assets	129,207	74,137
Operating lease right-of-use asset	439	735
Other assets	3,583	2,635
Total assets	$ 133,229	$ 77,507
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,444	$ 2,298
Accrued liabilities	5,863	2,291
Operating lease liability, current portion	429	338
Total current liabilities	10,736	4,927
Operating lease liability, net of current portion	116	441
Other long-term liabilities	—	26
Total liabilities	10,852	5,394
Commitments and contingencies		
Convertible preferred stock	—	126,756
Stockholders' equity (deficit):		
Common stock	—	—
Additional paid-in-capital	220,615	3,684
Accumulated other comprehensive income	82	—
Accumulated deficit	(98,320)	(58,327)
Total stockholders' equity (deficit)	122,377	(54,643)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 133,229	$ 77,507