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): August 11, 2026

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** **(Address of Principal Executive Offices)**	**92122** **(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 August 11, 2026, Aardvark Therapeutics, Inc. issued a press release reporting its financial results for the second quarter ended June 30, 2026, and providing 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 August 11, 2026.
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: August 11, 2026

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

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

Assessing unblinded Phase 3 HERO and OLE data for ARD-101 in PWS in the third quarter of 2026 to support an informed determination of next steps

Remains in active discussions with the FDA to support resolution of the clinical hold for ARD-101 program

$73.9 million in cash, cash equivalents and short-term investments as of June 30, 2026, supports projected operations into late 2027

SAN DIEGO, August 11, 2026 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark or the Company) (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, 2026, and provided pipeline and business updates.

“Patients and families in the PWS community are at the center of every decision we make, and our team is laser focused on establishing a clear path forward for ARD-101 in PWS,” said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “Over the last several months, we have continued to work collaboratively with the FDA. Additionally in the third quarter of this year, we are assessing the unblinded data from the HERO and OLE trials, which will allow us to understand the totality of the efficacy and safety results generated to date.”

Pipeline Updates

- Aardvark is assessing the unblinded clinical data accumulated to date across both the HERO (Hunger Elimination or Reduction Objective) trial and the OLE (Open Label Extension) trial to assess the totality of available efficacy and safety data and to support an informed determination of next steps for the ARD-101 program. In June 2026, the Company terminated the HERO and the OLE trial and does not currently intend to resume these trials as previously designed.
- In May 2026, the Company announced that the U.S. Food and Drug Administration (FDA) placed a full clinical hold on its investigational new drug application (IND) for ARD-101, related to the Company’s previously announced voluntary pause. The clinical hold applies to all previously ongoing clinical studies under the IND, including the Phase 3 HERO trial evaluating ARD-101 for the treatment of hyperphagia in patients with Prader-Willi Syndrome (PWS) and the Phase 3 OLE trial.

Second Quarter 2026 Financial Highlights

- **Cash Position:** As of June 30, 2026, Aardvark had cash, cash equivalents and short-term investments of $73.9 million, compared to $91.2 million as of March 31, 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 into late 2027.
- **Research & Development (R&D):** R&D expenses for the second quarter of 2026 were $10.5 million, compared to $13.1 million for the second quarter of 2025. The $2.7 million decrease for the three months ended June 30, 2026 as compared to the three months ended June 30, 2025 resulted primarily from a decrease of $3.3 million for external expenses incurred for CMC, clinical and toxicology studies primarily related to the development of ARD-101 as a result of the voluntary pause of all of our clinical trials and the subsequent clinical hold on our IND for ARD-101, offset by a $0.7 million increase in personnel-related costs due to increased headcount and bonuses prior to the workforce reduction implemented in June 2026.
- **General & Administrative (G&A):** G&A expenses for the second quarter of 2026 were $4.6 million, compared to $2.7 million for the second quarter of 2025. The $1.9 million increase for the three months ended June 30, 2026 as compared to the three months ended June 30, 2025 included additional public company operating costs and resulted primarily from an increase in personnel-related costs due to year-over-year increased headcount prior to the workforce reduction implemented in June 2026 associated with the voluntary pause of all of our clinical trials and the subsequent clinical hold on our IND for ARD-101, bonuses and $0.5 million in severance expense.
- **Net loss:** Aardvark reported a net loss of $14.4 million for each of the second quarters of 2026 and 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 (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. 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, paused 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 Aardvark’s anticipated cash runway, Aardvark’s discussions with the FDA, Aardvark’s unblinding and assessment of HERO and OLE trial data, 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: uncertainties related to potential delays in the commencement, recommencement, enrollment and completion of clinical trials and any additional actions that may be required by 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 Quarterly Report on Form 10-Q for the quarter ended June 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 and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 10,455	$ 13,145	$ 27,022	$ 20,900
General and administrative	4,629	2,703	10,526	5,418
Total operating expenses	15,084	15,848	37,548	26,318
Loss from operations	(15,084)	(15,848)	(37,548)	(26,318)
Total other income, net	697	1,481	1,573	2,641
Net loss	$ (14,387)	$ (14,367)	$ (35,975)	$ (23,677)
Net loss per share of common stock, basic and diluted	$ (0.66)	$ (0.66)	$ (1.65)	$ (1.36)
Weighted-average shares used in net loss per share calculation	21,846,251	21,690,275	21,831,206	17,465,965

Aardvark Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and par value data)

	June 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 73,849	$ 47,051
Short-term investments	21	62,976
Prepaid expenses and other current assets	6,791	1,859
Total current assets	80,661	111,886
Operating lease right-of-use asset	626	355
Other assets	173	4,940
Total assets	$ 81,460	$ 117,181
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,086	$ 2,072
Accrued liabilities	3,900	8,035
Operating lease liability, current portion	401	441
Total current liabilities	6,387	10,548
Operating lease liability, net of current portion	276	—
Total liabilities	6,663	10,548
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized at June 30, 2026 and December 31, 2025; no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock, $0.00001 par value; 490,000,000 shares authorized at June 30, 2026 and December 31, 2025; 21,884,158 and 21,815,353 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in-capital	226,690	222,470
Accumulated other comprehensive income	—	81
Accumulated deficit	(151,893)	(115,918)
Total stockholders' equity	74,797	106,633
Total liabilities and stockholders' equity	$ 81,460	$ 117,181