
**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): October 22, 2026

Aardvark Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-42513
(Commission File Number)

82-1606367
(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 8.01 Other Events.

On October 22, 2026, Aardvark Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration lifted the clinical hold on the Company’s Investigational New Drug application for ARD-101 for the treatment of hyperphagia in Prader-Willi Syndrome and announcing the Company will host a live conference call for investors on October 23, 2026 at 8:00 a.m. ET. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 22, 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: October 22, 2026

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



Aardvark Therapeutics Announces FDA Has Lifted the Clinical Hold on ARD-101 for the Treatment of Prader-Willi Syndrome and Will Host Webcast to Review the Available Exploratory Phase 3 HERO/OLE Data

Clinical development of ARD-101 for hyperphagia in Prader-Willi Syndrome (PWS) may resume

Aardvark will host a webcast to review available dataset from the terminated Phase 3 HERO trial and OLE trial on Friday, October 23, 2026, at 8:00 a.m. EST

SAN DIEGO, Oct. 22, 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 announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Company's Investigational New Drug application for ARD-101 for the treatment of hyperphagia in PWS.

"We are pleased that the FDA has lifted the clinical hold on ARD-101, allowing us to continue advancing our clinical development program," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "With strong alignment and collaboration with the FDA, we completed the work necessary to allow for the resumption of clinical studies. People living with PWS and their families continue to face profound unmet need, and we look forward to working with the FDA as we advance ARD-101."

On February 27, 2026, Aardvark voluntarily paused dosing in the Phase 3 Hunger Elimination or Reduction Objective (HERO) trial and its open-label extension (OLE) trial following reversible electrocardiogram (ECG) changes observed during routine safety monitoring in a separate study in healthy volunteers. In May 2026, the FDA placed a clinical hold on the HERO trial and OLE trial. In alignment with the FDA, the Company conducted a thorough ECG study in additional healthy volunteers and an in vitro cardiac sodium channel (NaV1.5) study. No cardiac events were observed in the recently completed ECG study at ARD-101 doses of 200 mg and 400 mg twice daily.

Aardvark plans to resume clinical development of ARD-101 in patients with PWS following additional anticipated engagement and alignment with the FDA on the Phase 3 trial design. As previously announced, Aardvark unblinded the data accumulated across both the HERO trial and OLE trial to assess the totality of available efficacy and safety data.

Conference Call and Webcast

The Company will host a live conference call and webcast for investors to discuss data from the terminated HERO and OLE trials tomorrow, October 23, 2026, at 8:00 AM ET. To access the live conference call, participants may register [here](#). To access the live webcast and subsequent archived recording of this event, please visit the Investors section of Aardvark's website.

About ARD-101

ARD-101 is an oral, small-molecule therapeutic designed to stimulate the release of gut-peptide hormones through activation of bitter taste receptors. ARD-101 is being developed as a treatment for hyperphagia associated with Prader-Willi Syndrome, a rare genetic disorder characterized by insatiable hunger.

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, the path forward for ARD-101, including the anticipated resumption of the clinical development of ARD-101 and any further engagement and alignment with the FDA prior to such resumption, 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: the risk that the FDA may not agree with Aardvark's proposed Phase 3 program or may require additional studies; limitations in interpreting data from the HERO trial and its OLE trial, which were terminated early and were not powered to assess efficacy; 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; the risk that Aardvark may use its capital resources sooner than expected; 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, filed with the Securities and Exchange Commission on August 11, 2026. 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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