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

April 28, 2021
Date of Report (Date of earliest event reported)

Adverum Biotechnologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36579**	**20-5258327**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

800 Saginaw Drive
Redwood City, CA 94063
(Address of principal executive offices, including zip code)

(650) 656-9323
(Registrant's telephone number, including area code)

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 obligations 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 communication 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	ADVM	Nasdaq Global Market

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 April 28, 2021, Adverum Biotechnologies, Inc. issued a press release providing an update on its INFINITY trial evaluating ADVM-022 in patients with diabetic macular edema, announcing a Suspected Unexpected Serious Adverse Reaction (SUSAR) of hypotony (clinically-relevant decrease in ocular pressure). This event occurred 30 weeks after randomization in one patient treated with a single intravitreal injection of the high dose (6×10^{11} vg/eye) who has developed hypotony, with panuveitis and loss of vision in the treated eye. A copy of such press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated April 28, 2021, providing an update on Adverum Biotechnologies, Inc.'s INFINITY trial evaluating ADVM-022 in patients with diabetic macular edema.
104	Cover Page Interactive Data File (formatted as Inline XBRL and included in Exhibit 101)

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.

Adverum Biotechnologies, Inc.

Date: April 28, 2021

By: /s/ Laurent Fischer, M.D.
Laurent Fischer, M.D.
Chief Executive Officer

Exhibit 99.1

Adverum Biotechnologies Provides Update on the INFINITY Trial Evaluating ADVM-022 in Patients with Diabetic Macular Edema

REDWOOD CITY, Calif., April 28, 2021 (GLOBE NEWSWIRE) - Adverum Biotechnologies, Inc. (Nasdaq: ADVM) announced a Suspected Unexpected Serious Adverse Reaction (SUSAR) of hypotony (clinically-relevant decrease in ocular pressure) in its INFINITY clinical trial evaluating ADVM-022 gene therapy for the treatment of diabetic macular edema (DME). This event occurred 30 weeks after randomization in one patient treated with a single intravitreal injection of the high dose (6 x 10^11 vg/eye) of ADVM-022 who has developed hypotony, with panuveitis and loss of vision in the treated eye.

In the interests of patient safety, Adverum has decided to immediately unmask the INFINITY Phase 2 study to better understand this event and to help identify and manage any similar potential risk to other patients in this study, which completed patient dosing in December 2020. Additionally, the company is conducting a thorough review of data from the ADVM-022 program and plans to report its findings as the analysis progresses.

“The safety of every patient who is participating in our clinical studies with our gene therapy is the utmost priority for us at Adverum,” said Laurent Fischer, M.D., chief executive officer of Adverum. “We are fully committed to thoroughly assessing this case and ongoing monitoring of this patient and all patients treated with ADVM-022 with our investigators, data monitoring committee (DMC), scientific advisory board, and healthcare authorities.”

The INFINITY study is evaluating two doses of a single intravitreal (IVT) injection of ADVM-022 gene therapy, either a high dose 6 x 10^11 vg/eye or low dose 2 x 10^11 vg/eye. As of December 2020, the INFINITY study was fully enrolled, and all patients completed dosing of the single IVT injection of ADVM-022. All patients continue to be evaluated regularly during the monitoring phase of this study. Adverum is working closely with the DMC and the study sites to proactively develop additional recommendations for patient monitoring and management. All clinical trial sites, as well as the U.S. Food and Drug Administration (FDA), have been advised of this case.

About the INFINITY Phase 2 Trial of ADVM-022 in DR/DME
INFINITY is a Phase 2, multi-center, randomized, double-masked, active comparator-controlled trial designed to assess a single intravitreal (IVT) injection of ADVM-022 in patients with diabetic macular edema (DME), the most common cause of vision loss in patients with diabetic retinopathy (DR).

The INFINITY trial enrolled 36 patients and is designed to demonstrate superior control of disease activity following a single IVT injection of ADVM-022 compared to a single aflibercept injection, as measured by time to worsening of DME disease activity. Participants in this double-masked trial were randomized to one of three arms for their study eye treatment: Arm 1 received high dose (6 x 10^11 vg/eye) of ADVM-022, Arm 2 received low dose (2 x 10^11 vg/eye) of ADVM-022, and Arm 3 received aflibercept at a dose of 2 mg. Additional objectives include assessments of treatment burden, visual acuity, retinal anatomy, and safety outcomes. For additional information about the INFINITY trial, please visit www.clinicaltrials.gov using Identifier NCT#04418427 or www.INFINITYclinicaltrial.com.

About Adverum Biotechnologies
Adverum Biotechnologies (Nasdaq: ADVM) is a clinical-stage gene therapy company targeting unmet medical needs in serious ocular and rare diseases. Adverum is advancing the clinical development of its novel gene therapy candidate, ADVM-022, as a one-time, intravitreal injection for the treatment of patients with wet age-related macular degeneration and diabetic macular edema. For more information, please visit www.adverum.com.

Forward-Looking Statements
Statements contained in this press release regarding the events or results that may occur in the future are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks described in Adverum’s Quarterly Report on Form 10-K for the year ended December 31, 2020 and any subsequent filings with the SEC under the heading “Risk Factors.” All forward-looking statements contained in this press release speak only as of the date on which they were made. Adverum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Relations Contacts
Myesha Lacy
Adverum Biotechnologies, Inc.
T: 650-649-1257
E: mlacy@adverum.com

Amy Figueroa
Adverum Biotechnologies, Inc.
T: 650-823-2704
E: afigueroa@adverum.com

Media Contact
Andrea Cohen
Sam Brown Inc.
T: 917-209-7163
E: andreacohen@sambrown.com

# # #