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

November 5, 2020
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 2.02 Results of Operations and Financial Condition.

On November 5, 2020, Adverum Biotechnologies, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020, and providing a corporate update. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this report, including the exhibit hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Adverum Biotechnologies, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 5, 2020, announcing Adverum Biotechnologies, Inc. financial results for the quarter ended September 30, 2020, and providing a corporate update.
104	The cover page of this report has been formatted in Inline XBRL

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: November 5, 2020

By: /s/ Laurent Fischer
Laurent Fischer, Chief Executive Officer

Exhibit 99.1

Adverum Biotechnologies Reports Recent Business Progress and Third Quarter 2020 Financial Results

-- Company to host conference call and webcast with KOLs to discuss new data from Cohorts 1-4 of OPTIC Phase 1 trial of ADVM-022 for wet AMD on November 14, 2020 at 7:30 am PT –

-- FDA removes partial clinical hold on ADVM-022 --

-- Planning to start a pivotal trial for ADVM-022 in wet AMD mid-2021 --

-- INFINITY Phase 2 trial for ADVM-022 enrolling patients with DME; Data expected 2H21 --

REDWOOD CITY, CA, November 5, 2020 – Adverum Biotechnologies, Inc. (Nasdaq: ADVM), a clinical-stage gene therapy company targeting unmet medical needs in ocular and rare diseases, today reported recent business progress and financial results for the third quarter ended September 30, 2020.

“We are continuing execution and progress across our organization as preparations are underway for us to become a late-stage gene therapy company next year with two programs underway for ADVM-022, in wet AMD and DME,” said Laurent Fischer, M.D., chief executive officer of Adverum. “We believe that ADVM-022 has the potential to reduce the treatment burden for the millions of patients living worldwide with these chronic ocular diseases with a potential “one and done” treatment. The FDA’s recent removal of the partial clinical hold is an important milestone achievement as we intend to initiate our pivotal trial for ADVM-022 in wet AMD in mid-2021. Based on the positive data from OPTIC in wet AMD and the progress with INFINITY in DME, we are preparing to meet with regulators to discuss our development plans for ADVM-022 in order to accelerate our development, manufacturing, and future commercial launch plans for this therapy. We continue to expand our team of leaders as we establish world-class capabilities across operational functions to plan for future opportunities to deliver novel gene therapies to patients.”

Recent Progress

- Adverum has received notification that the U.S. Food and Drug Administration (FDA) has removed the partial clinical hold on ADVM-022 after the company provided the agency with the requested information related to CMC. The partial hold did not affect the INFINITY Phase 2 trial for DME or current doses evaluated in the OPTIC Phase 1 trial for wet AMD. Adverum plans to meet with the agency to discuss the company's plans for pivotal trials to support the filing of a Biologics License Application (BLA) for ADVM-022 in wet AMD.
- Adverum raised approximately $203.4 million in net proceeds from an underwritten public offering in August 2020.
- Thomas Kochy joined Adverum as vice president, commercial and program strategy. Mr. Kochy has program leadership, product marketing, and sales management expertise, including 10 years of experience in Genentech's Ophthalmology franchise.
- Christopher J. Morrison, Ph.D. joined Adverum as vice president, process science. Dr. Morrison has 10 years of pharmaceutical industry experience and has a background in gene therapy, recombinant adeno-associated viral vector (rAAV) process development, and clinical manufacturing.

Future Plans
ADVM-022 in wet AMD
- Present new clinical data from Cohorts 1-4 of OPTIC Phase 1 trial during KOL call and webcast on November 14, 2020
- Initiate a pivotal trial mid-2021

ADVM-022 in DME
- Present clinical data from INFINITY Phase 2 trial in the second half of 2021

Manufacturing
- Initiating process scale-up from 200L to 1000L scale to support the potential future commercial product launch of ADVM-022
- Beginning to plan for in-house GMP capabilities with initiation of site selection

Adverum Webcast with Key Opinion Leaders:
On Saturday, November 14, the Company will host a webcast with Key Opinion Leaders to review new OPTIC data in lieu of a quarterly conference call this quarter.
Date: November 14, 2020
Time: 7:30 – 9:00 am PT (10:30 am – 12:00 pm ET)
Presenters:
- Carl Regillo, M.D., F.A.C.S, chief of retina services at Wills Eye Hospital and investigator in the OPTIC Phase 1 trial
- Steven Yeh, M.D., associate professor, director, section of uveitis and ocular immunology, Emory Eye Center

- David S. Boyer, M.D., senior partner, Retina-Vitreous Associates Medical Group and adjunct clinical professor of ophthalmology, University of Southern California/ Keck School of Medicine, Los Angeles, investigator in the OPTIC Phase 1 trial

The live video webcast will be accessible under Events and Presentations in the Investors section of the company's website. To participate in the conference call, dial 1-877-705-6003 (domestic) or 1-201-493-6725 (international) and refer to the “Adverum Biotechnologies’ OPTIC Clinical Data Discussion Conference Call.” It is recommended call participants dial in 15 minutes in advance. The archived audio webcast will be available on the Adverum website following the call and will be available for 30 days.

Presentation of Existing OPTIC Data:
Event: Retina Subspecialty Day 2020 Virtual Meeting
Title: Intravitreal Gene Therapy with ADVM-022 for Neovascular AMD: OPTIC Phase 1 Study
Date: November 13, 2020
Time: 2:15 pm PT
Presenter: Carl Regillo, M.D., F.A.C.S, chief of retina services at Wills Eye Hospital
Presentation: At the beginning of Dr. Regillo’s presentation, Adverum plans to post the presentation under Events and Presentations in the Investors section of the company’s website.

Presentation of Existing OPTIC Data:
Event: AAO 2020 Virtual Meeting
Title: Phase 1 Study of Intravitreal Gene Therapy with ADVM-022 for Neovascular AMD (OPTIC Trial Cohorts 1-4, from the August 10, 2020 data presentation)
Date: November 14-17, 2020
Presenter: Arshad M. Khanani, M.D., M.A., managing partner and director of clinical research, Sierra Eye Associates, clinical associate professor of ophthalmology, University of Nevada
Presentation: On or before November 13, 2020 the virtual presentations will be available on demand to AAO participants, and Adverum plans to post the presentation under Events and Presentations in the Investors section of the company’s website.

COVID-19

To date, Adverum has experienced limited impact from COVID-19 on its operations and ongoing clinical programs, including the OPTIC and INFINITY clinical trials. The company is continuing to monitor and attempt to address or limit the potential impacts of COVID-19 on its employees and operations, patient safety, patient enrollment, continued participation of patients already enrolled in the company's clinical studies, protocol compliance, data quality, and overall study integrity.

Financial Results for the Three Months Ended September 30, 2020

- **Cash, cash equivalents and short-term investments** were $454.5 million as of September 30, 2020, including approximately $203.4 in net proceeds from an underwritten public offering in August 2020, compared to $166.0 million as of December 31, 2019. Adverum expects this quarter-end cash position to fund operations into mid-2022.
- **Research and development expenses** were $16.7 million for the three months ended September 30, 2020, compared to $9.9 million for the same period in 2019. Research and development expenses increased primarily due to higher personnel-associated costs, material production costs, and laboratory expenses. Stock-based compensation expense included in research and development expenses was $2.1 million for the third quarter of 2020.
- **General and administrative expenses** were $11.4 million for the three months ended September 30, 2020, compared to $7.4 million for the same period in 2019. General and administrative expenses increased primarily due to higher personnel-associated costs as well as depreciation expense for Adverum's new headquarters. Stock-based compensation expense included in general and administrative expenses was $4.0 million for the third quarter of 2020.
- **Net loss** was $27.8 million, or $0.31 per basic and diluted share, for the three months ended September 30, 2020, compared to $16.1 million, or $0.25 per basic and diluted share, for the same period in 2019.

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 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. Such statements include, but are not limited to statements regarding: the potential for ADVM-022 in treating patients with wet AMD and DME; Adverum's expectations that it will present additional data from all four cohorts of the OPTIC Phase 1 trial for ADVM-022 in wet AMD in November 2020; Adverum's expectations as to its plans to advance ADVM-022 in wet AMD by initiating a pivotal trial mid-2021 and in DME by continuing to enroll patients in the INFINITY trial, Adverum's expectations that it will present data from the INFINITY trial in the second half of 2021; Adverum's expectations that it will accelerate its development, manufacturing, and commercial launch plans for ADVM-022; and Adverum's expectations that its current cash position will fund its operations into mid-2022. All of these statements are based on certain assumptions made by Adverum on current conditions, expected future developments and other factors Adverum believes are appropriate in the circumstances. Adverum may not achieve any of these in a timely manner, or at all, or otherwise carry out the intentions or meet the expectations disclosed in its forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks inherent to, without limitation: Adverum's novel technology, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the results of early clinical trials not always being predictive of future results; the potential for preliminary or interim results of clinical trials to change as the clinical trial continues or in connection with the preparation and analysis of final results; the potential for future complications or side effects in connection with use of ADVM-022; obtaining regulatory approval for gene therapy product candidates; enrolling patients in clinical trials; reliance on third parties for conducting the OPTIC and INFINITY trials and vector production; the effects of the COVID-19 pandemic on the company's operations and on the company's ongoing clinical trials; and ability to fund operations through completion of the OPTIC and INFINITY trials and thereafter. Risks and uncertainties facing Adverum are described more fully in Adverum's Form 10-Q filed with the SEC on November 5, 2020 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 and Media Inquiries:
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Adverum Biotechnologies, Inc.
Consolidated Balance Sheets
(In thousands)

	September 30 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 72,696	$ 65,897
Short-term investments	381,766	100,138
Prepaid expenses and other current assets	5,238	9,835
Total current assets	459,700	175,870
Operating lease right-of-use asset	19,698	20,963
Property and equipment, net	27,295	24,884
Restricted cash	999	999
Deposit and other long-term assets	19	11
Total assets	$ 507,711	$ 222,727
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,034	$ 4,103
Accrued expenses and other current liabilities	8,642	11,271
Lease liability, current portion	4,435	4,034
Total current liabilities	16,111	19,408
Lease liability, net of current portion	26,752	28,214
Other noncurrent liabilities	136	148
Total liabilities	42,999	47,770
Stockholders' equity:		
Common stock	10	7
Additional paid-in capital	930,211	560,704
Accumulated other comprehensive loss	(605)	(725)
Accumulated deficit	(464,904)	(385,029)
Total stockholders' equity	464,712	174,957
Total liabilities and stockholders' equity	$ 507,711	$ 222,727

(1) Derived from Adverum's annual audited consolidated financial statements.

Adverum Biotechnologies, Inc.
Consolidated Statements of Operations
(In thousands except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration and license revenue	$ -	$ 250	$ -	$ 250
Operating expenses:				
Research and development	16,653	9,944	50,581	29,045
General and administrative	11,351	7,389	30,989	20,097
Total operating expenses	28,004	17,333	81,570	49,142
Operating loss	(28,004)	(17,083)	(81,570)	(48,892)
Other income, net	235	965	1,695	3,331
Net loss	(27,769)	(16,118)	(79,875)	(45,561)
Net loss per share — basic and diluted	$ (0.31)	$ (0.25)	$ (0.99)	$ (0.71)
Weighted-average common shares outstanding - basic and diluted	88,867	64,484	80,995	63,764