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): January 10, 2025

Arvinas, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38672**	**47-2566120**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5 Science Park **395 Winchester Ave.** **New Haven, Connecticut**	**06511**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 535-1456

Not applicable
(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 (*see* General Instruction A.2. below):

☐ 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 $0.001 per share	**ARVN**	**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 7.01 Regulation FD Disclosure.

On January 10, 2025, Arvinas, Inc. (the "Company"), announced updated guidance for the planned first- and second-line Phase 3 combination clinical trials for vepdegestrant in patients with locally advanced or metastatic estrogen receptor ("ER") positive ("ER+")/human epidermal growth factor receptor 2 ("HER2") negative ("HER2-"; "ER+/HER2-") breast cancer, certain upcoming milestones anticipated in 2025 and provided a corporate update.

The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information in this Item 7.01, including Exhibit 99.1 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 set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 10, 2025, the Company announced updated guidance for the planned first- and second-line Phase 3 combination clinical trials for vepdegestrant in patients with locally advanced or metastatic ER+/HER2- breast cancer, certain upcoming milestones anticipated in 2025 and provided a corporate update. Vepdegestrant is an investigational, orally bioavailable PROteolysis TArgeting Chimera ("PROTAC") ER degrader designed to harness the body's natural protein disposal system to specifically target and degrade the ER and is being co-developed by the Company and Pfizer, Inc. ("Pfizer").

The Company is on track to announce, along with Pfizer, topline data for the VERITAC-2 Phase 3 monotherapy clinical trial in patients with second-line-plus ER+/HER2- metastatic breast cancer ("mBC") in the first quarter of 2025. In addition, as part of the Company's global collaboration with Pfizer, in 2025, pending emerging data and regulatory feedback, the companies plan to initiate two new Phase 3 combination trials of vepdegestrant in patients with ER+/HER2- mBC:

- a first-line Phase 3 combination clinical trial with Pfizer's novel investigational CDK4 inhibitor, atirmociclib; and
- a second-line Phase 3 combination clinical trial with a CDK4/6 inhibitor.

With the prioritization of the vepdegestrant plus atirmociclib combination for the first-line setting, the VERITAC-3 clinical trial evaluating vepdegestrant plus palbociclib in the first-line will not proceed beyond the study lead-in.

The Company also announced that it recently initiated a Phase 1 clinical trial with PROTAC leucine-rich repeat kinase 2 ("LRRK2") protein degrader ARV-102 in patients with Parkinson's disease and that, in 2025, the Company plans to:

- present single-ascending dose data from the ongoing Phase 1 clinical trial of ARV-102 in healthy volunteers in an oral session at the Alzheimer's Disease/Parkinson's Disease conference in Vienna, Austria, taking place from April 1-4, 2025;
- complete enrollment and present initial data from the ongoing Phase 1 clinical trial of ARV-102 in patients with Parkinson's disease;
- present initial data from the ongoing Phase 1 clinical trial of ARV-393, the Company's PROTAC targeting the B-cell lymphoma 6, in patients with B-cell lymphomas (NCT06393738); and
- file an Investigational New Drug ("IND") application for the Company's PROTAC Kirsten rat sarcoma ("KRAS") G12D degrader.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential plans related to and timing of initiation of clinical trials and presentation of data from clinical trials of vepdegestrant, ARV-393 and ARV-102 as well as filing of an IND for the Company's KRAS G12D degrader. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's strategy, future operations, prospects, plans and objectives of management, are forward-looking statements. The word "plan," and similar expressions are intended to identify forward-looking

statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements the Company makes as a result of various risks and uncertainties, including the important factors discussed the important factors discussed in the "Risk Factors" sections contained in the Company's quarterly and annual reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this Current Report on Form 8-K reflect the Company's current views with respect to future events, and the Company assumes no obligation to update any forward-looking statements except as required by applicable law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release, dated January 10, 2025
104	Cover Page Interactive Data File (formatted as 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.

ARVINAS, INC.

Date: January 10, 2025

By: /s/ Andrew Saik

Andrew Saik
Chief Financial Officer

Exhibit 99.1

Arvinas Updates Guidance for First- and Second-Line Phase 3 Combination Trials with Vepdegestrant, Highlights Upcoming Milestones, and Provides Corporate Update

– Vepdegestrant to be combined with Pfizer's novel investigational CDK4 inhibitor atirmociclib in a first-line Phase 3 trial planned to initiate in 2025; a second-line Phase 3 combination trial will combine vepdegestrant with a CDK4/6 inhibitor, also planned to initiate in 2025 –

– Topline data from the monotherapy Phase 3 VERITAC-2 trial of vepdegestrant anticipated in 1Q25 –

– The Company recently initiated a Phase 1 trial with PROTAC LRRK2 degrader ARV-102 in patients with Parkinson's disease –

– Data disclosures anticipated from multiple clinical and pre-clinical programs, including ARV-102 and ARV-393, and planned IND submission for a PROTAC KRAS G12D degrader in 2025 –

NEW HAVEN, Conn., Jan. 10, 2025 -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today announced updated guidance for the planned first- and second-line combination clinical trials for vepdegestrant in patients with locally advanced or metastatic estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) breast cancer, highlighted key upcoming milestones and provided a corporate update.

"We are on the cusp of a major transformation in 2025, with the potential to provide significant benefit to patients and meaningful value to our stockholders," said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. "We are on track to report topline results from our first Phase 3 trial in the first quarter and to initiate two additional Phase 3 trials by the end of the year. In the first half of 2025, we plan to present the first-in-human data from ARV-102, our PROTAC LRRK2 degrader, which we believe will highlight the potential value that our PROTAC degraders may offer for patients with neurodegenerative diseases. And finally, we plan to share initial data from our Phase 1 trial with ARV-393, our PROTAC BCL6 degrader, which will provide an early look the tolerability and efficacy in patients with B-cell lymphomas."

Select milestones anticipated in 2025

Vepdegestrant: Oral PROTAC ER degrader

As part of Arvinas' global collaboration with Pfizer, in 2025 the companies plan to:

- Announce topline data for the VERITAC-2 Phase 3 monotherapy clinical trial in patients with second-line-plus ER+/HER2- metastatic breast cancer (mBC) (1Q25).
- Initiate two new Phase 3 combination trials in patients with ER+/HER2- mBC (pending emerging data and regulatory feedback):
    - First-line Phase 3 combination trial with Pfizer's novel investigational CDK4 inhibitor, atirmociclib.
    - Second-line Phase 3 combination trial with a CDK4/6 inhibitor.

With the prioritization of the vepdegestrant plus atirmociclib combination for the first-line setting, the VERITAC-3 trial evaluating vepdegestrant plus palbociclib in the first-line will not proceed beyond the study lead-in.

ARV-102: Oral PROTAC LRRK2 degrader

- Present single-ascending dose data from the ongoing Phase 1 clinical trial in healthy volunteers in an oral session at the Alzheimer's Disease/Parkinson's Disease (AD/PD) conference in Vienna, Austria (April 1-4, 2025).
- Complete enrollment and present initial data from the ongoing Phase 1 clinical trial in patients with Parkinson's disease.

ARV-393: Oral PROTAC BCL6 degrader

- Present initial data from the ongoing Phase 1 clinical trial in patients with B-cell lymphomas (NCT06393738).

Novel PROTAC KRAS G12D degrader

- File an Investigational New Drug (IND) application.

Corporate update

Alex Santini, Arvinas' Senior Vice President, Global and U.S. Market Access, has been appointed interim Chief Commercial Officer, effective January 17, 2025. Mr. Santini joined Arvinas in 2023 with more than 30 years of experience managing and leading commercial organizations. Previously, he was Executive Vice President, Chief Commercial Officer, at Lexicon Pharmaceuticals. Prior to Lexicon, Mr. Santini was Executive Vice President, U.S. Market Access at Bayer, where he served on the U.S. Executive Committee. Mr. Santini's prior experience also includes serving as Senior Vice President, Market Access at Nektar Therapeutics, and he began his career at Berlex Laboratories, where he served in roles of increasing responsibility in the commercial organization.

John Northcott, Chief Commercial Officer, is leaving the Company for personal reasons, effective January 17, 2025.

"Our commercial organization couldn't be in a better position, and I look forward to working closely with Alex," continued Dr. Houston. "He has been a highly valued member of the Arvinas team for multiple years, and his well-established ability to build and lead an outstanding commercial team will be invaluable as we prepare for our potential first launch alongside our partners at Pfizer. We thank John for his contributions to the business, particularly his efforts to begin building a strong commercial organization for launch."

About Vepdegestrant

Vepdegestrant is an investigational, orally bioavailable PROTAC protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with ER positive (ER+)/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Vepdegestrant is being developed as a potential monotherapy and as part of combination therapy across multiple treatment settings for ER+/HER2- metastatic breast cancer.

In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will share worldwide development costs, commercialization expenses, and profits.

The U.S. Food and Drug Administration (FDA) has granted vepdegestrant Fast Track designation as a monotherapy in the treatment of adults with ER+/HER2- locally advanced or metastatic breast cancer previously treated with endocrine-based therapy.

About Arvinas
Arvinas (Nasdaq: ARVN) is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases. Through its PROTAC® (PROteolysis Targeting Chimera) protein degrader platform, the Company is pioneering the development of protein degradation therapies designed to harness the body's natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. Arvinas is currently progressing multiple investigational drugs through clinical development programs, including vepdegestrant, targeting the estrogen receptor for patients with locally advanced or metastatic ER+/HER2- breast cancer; ARV-393, targeting BCL6 for relapsed/refractory non-Hodgkin Lymphoma; and ARV-102, targeting LRRK2 for neurodegenerative disorders. Arvinas is headquartered in New Haven, Connecticut. For more information about Arvinas, visit www.arvinas.com and connect on **LinkedIn** and **X**.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the plans and expected timing of initiation of two Phase 3 vepdegestrant combination clinical trials, in the first- and second-line settings, pending emerging data and regulatory feedback; the expected timing to report topline data from the VERITAC-2 Phase 3 monotherapy clinical trial of vepdegestrant; the potential to provide significant benefit to patients and meaningful value to stockholders in 2025; the plans and timing of presentation of first-in-human data from ARV-102 and the company's belief that such data will highlight the potential value that its PROTAC degraders may offer patients with neurodegenerative diseases; the plans and timing of sharing initial data from the company's Phase 1 clinical trial of ARV-393; and the plans and expected timing of filing an investigational new drug application for a PROTAC KRAS G12D degrader. All statements, other than statements of historical fact, contained in this press release, including statements regarding Arvinas' strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "goal," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Arvinas may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Arvinas makes as a result of various risks and uncertainties, including but not limited to: Arvinas' and Pfizer's performance of the respective

obligations with respect to Arvinas' collaboration with Pfizer; whether Arvinas and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant; whether Arvinas will be able to successfully conduct and complete development for its other product candidates, including whether Arvinas initiates and completes clinical trials for its product candidates and receives results from its clinical trials on its expected timelines or at all; Arvinas' ability to protect its intellectual property portfolio; whether Arvinas' cash and cash equivalent resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements, and other important factors discussed in the "Risk Factors" section of Arvinas' Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent other reports, including its quarterly reports, on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Arvinas' current views with respect to future events, and Arvinas assumes no obligation to update any forward-looking statements, except as required by applicable law. These forward-looking statements should not be relied upon as representing Arvinas' views as of any date subsequent to the date of this release.

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