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): February 14, 2022

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 February 14, 2022, Arvinas, Inc. (the "Company") issued a press release announcing completed data from the dose escalation portion of the Phase 1 clinical trial and interim data from the ARDENT Phase 2 dose expansion of its PROTAC® protein degrader bavdegalutamide (ARV-110) in men with metastatic castration-resistant prostate cancer. The Company will present the updated data on a conference call and webcast on February 17, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein 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 February 14, 2022, the Company announced completed data from the dose escalation portion of the Phase 1 clinical trial and interim data from the ARDENT Phase 2 dose expansion of bavdegalutamide in men with metastatic castration-resistant prostate cancer ("mCRPC") as of the abstract data cut-off date of August 26, 2021.

Efficacy

Across 140 biomarker-evaluable patients with ≥1 month of prostate-specific antigen ("PSA") follow-up in the completed Phase 1 dose escalation and ongoing Phase 2 ARDENT expansion cohort the Company reported evidence of anti-tumor activity and patient benefit, including:

- Reduced PSA levels greater than or equal to 50% ("PSA50") rate of 46% in patients with AR T878X/H875Y (where T878X = T878A or T878S) tumor mutations (n=26);
- Two confirmed RECIST (Response Evaluation Criteria in Solid Tumors) partial responses out of seven RECIST-evaluable patients with AR T878X/H875Y tumor mutations; and
- PSA50 rate of 26% (five of 19) in evaluable patients in the subgroup defined as "less pretreated" (having received only one prior novel hormonal agent and no prior chemotherapy). The "less pretreated" subgroup had a similar circulating tumor DNA molecular profile to the more pretreated, biomarker-defined subgroups in the ARDENT trial; a majority of patients with PSA50 declines in this group had tumors with the AR T878X/H875Y mutations.

Safety

As of the data cut-off date, bavdegalutamide had a manageable tolerability profile at the recommended Phase 2 dose ("RP2D") of 420 mg. The majority of treatment-related adverse events ("TRAEs") were Grade 1/2 and there were no Grade ≥4 TRAEs in the 113 patients treated at the RP2D. The most common TRAEs of any grade at the RP2D across the completed Phase 1 and the ongoing Phase 2 ARDENT expansion cohort were nausea (Grade 1/2: 42%; Grade 3: 1%), fatigue (Grade 1/2: 27%; Grade 3: 1%), vomiting (Grade 1/2: 23%; Grade 3: 1%), decreased appetite (Grade 1/2: 19%; Grade 3: 0), diarrhea (Grade 1/2: 15%; Grade 3: 2%), and alopecia (Grade 1/2: 11%).

The Company plans to initiate a pivotal trial by year end 2022 evaluating bavdegalutamide in patients with mCRPC who have progressed on or after novel hormonal agents and have tumors that harbor AR T878X/H875Y tumor mutations.

Additional data from the completed Phase 1 and interim results from the ongoing Phase 2 ARDENT trial will be presented on Thursday, February 17, 2022 at ASCO GU. The data cut-off date for data in the rapid abstract session and the poster session at ASCO GU was December 20, 2021.

Abstract details are as follows:

Abstract Title: Phase 1/2 study of ARV-110, an androgen receptor (AR) PROTAC degrader, in metastatic castration-resistant prostate cancer (mCRPC)

Session Title: Poster Session A: Prostate Cancer

Session Date: Thursday, February 17, 2022

Session Time: 2:30 – 4:00 p.m. ET

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 14, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL)

Forward-Looking Statements

This Current Report on Form 8-K, including the document furnished as Exhibit 99.1 hereto, contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of bavdegalutamide, the development and regulatory status of bavdegalutamide and the Company's other product candidates, and the timing of clinical trials and data from those trials and plans for registration for the Company's product candidates, and the potential commercialization of any of the Company's product candidates. 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 words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "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.

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 but not limited to: whether the Company and Pfizer, as applicable, will be able to successfully conduct and complete clinical development for ARV-471, bavdegalutamide, ARV-766 and the Company's other product candidates, including whether the Company initiates and completes clinical trials for the Company's product candidates, and receives results from the Company's clinical trials on the Company's expected timelines, or at all, and other important factors discussed in the "Risk Factors" sections contained in the Company's quarterly and annual reports on file with the 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 14, 2022

ARVINAS, INC.

By: /s/ Sean Cassidy
Sean Cassidy
Chief Financial Officer

Exhibit 99.1

Arvinas Announces New Data from Completed Phase 1 Dose Escalation and Ongoing Phase 2 ARDENT Expansion Cohort with Novel PROTAC® Degrader Bavdegalutamide (ARV-110) to be Presented at 2022 ASCO GU Meeting

– Bavdegalutamide demonstrated a 46% PSA_{50} rate in patients with metastatic castration-resistant prostate cancer (mCRPC) and androgen receptor (AR) T878X/H875Y tumor mutations –

– Arvinas plans to initiate a pivotal trial by year end 2022 evaluating bavdegalutamide in patients with mCRPC who have progressed on or after novel hormonal agents (NHAs) and have tumors that harbor AR T878X/H875Y mutations –

– Updated data to be presented in a rapid abstract session and a poster session at ASCO GU and Arvinas to hold conference call on Thursday, February 17 at 8:30 a.m. ET –

NEW HAVEN, Conn., Feb. 14, 2022 — Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today announced the presentation of new data showing that bavdegalutamide (also known as ARV-110), a novel PROTAC® protein degrader targeting the androgen receptor (AR), continues to provide evidence of anti-tumor activity and patient benefit in metastatic castration-resistant prostate cancer (mCRPC). These data show that bavdegalutamide reduced prostate-specific antigen (PSA) levels greater than or equal to 50% (PSA_{50}) in 46% of patients with tumors harboring AR T878X/H875Y (T878X = T878A or T878S) mutations. Updated Phase 1 and interim Phase 2 ARDENT data will be presented in both a rapid abstract session and a poster session on February 17, 2022, at the 2022 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium.

“These results are very encouraging and reinforce our conviction that bavdegalutamide has the potential to provide meaningful clinical benefit to patients with mCRPC who have progressed after treatment with novel hormonal agents and for whom few treatment options exist,” said John Houston, Ph.D., president and chief executive officer of Arvinas. “With particularly robust activity in a molecularly defined patient population, we believe there is a clear path forward to developing this novel treatment as a precision medicine and plan to initiate a pivotal trial by year end 2022.”

Highlights from the bavdegalutamide abstract (data cut-off date August 26, 2021):

Across 140 biomarker-evaluable patients with ≥1 month of PSA follow-up in the completed Phase 1 dose escalation and ongoing Phase 2 ARDENT expansion cohort:

- Evidence of anti-tumor activity and patient benefit, including:
  - PSA_{50} rate of 46% in patients with AR T878X/H875Y tumor mutations (n=26)
  - Two confirmed RECIST (Response Evaluation Criteria in Solid Tumors) partial responses out of seven RECIST-evaluable patients with AR T878X/H875Y tumor mutations
  - PSA_{50} rate of 26% (five of 19) in evaluable patients in the subgroup defined as “less pretreated” (having received only one prior novel hormonal agent and no prior chemotherapy). The “less pretreated” subgroup had a similar circulating tumor DNA molecular profile to the more pretreated, biomarker-defined subgroups in the ARDENT trial; a majority of patients with PSA_{50} declines in this group had tumors with the AR T878X/H875Y mutations

- Bavdegalutamide had a manageable tolerability profile at the recommended Phase 2 dose (RP2D) of 420 mg. The majority of treatment-related adverse events (TRAEs) were Grade 1/2 and there were no Grade ≥4 TRAEs in the 113 patients treated at the RP2D.
    - The most common TRAEs of any grade at the RP2D across Phase 1 and the ongoing phase 2 ARDENT expansion cohort were nausea (Grade 1/2: 42%; Grade 3: 1%), fatigue (Grade 1/2: 27%; Grade 3: 1%), vomiting (Grade 1/2: 23%; Grade 3: 1%), decreased appetite (Grade 1/2: 19%; Grade 3: 0), diarrhea (Grade 1/2: 15%; Grade 3: 2%), and alopecia (Grade 1/2: 11%).

“Novel hormonal agents have become standard of care in castration-sensitive prostate cancer and there is a need for novel AR therapies with the potential to provide benefit for patients with mCRPC and tumors that have developed resistance,” said Ron Peck, M.D., chief medical officer at Arvinas. “As an oncologist, I’m particularly excited by a precision medicine approach with the potential to identify patients who are most likely to respond to bavdegalutamide.”

Additional data from the completed Phase 1 and interim results from the ongoing Phase 2 ARDENT trial will be presented on Thursday, February 17, 2022. The cut-off date for data in the rapid abstract session and the poster session was December 20, 2021.

Poster presentation:

- **Poster Title:** Phase 1/2 study of ARV-110, an androgen receptor (AR) PROTAC degrader, in metastatic castration-resistant prostate cancer (mCRPC)
- **Session:** Poster Session A: Prostate Cancer
    - **Date:** Thursday, February 17, 2022
    - **Time:** 2:30 – 4:00 p.m. ET

Rapid abstract session (7:45 – 8:45 p.m. ET):

- **Rapid Abstract Title:** Rapid Abstract Session A: Prostate Cancer
    - **Date:** Thursday, February 17, 2022
    - **Time:** 7:55 – 8:00 p.m. ET

The full abstract can be found at the official ASCO Genitourinary Cancers Symposium website.

Arvinas Webcast Investor Meeting Arvinas will host a conference call and webcast Thursday, February 17, 2022, at 8:30 a.m. ET, to discuss the completed Phase 1 dose escalation data and interim data from the Phase 2 ARDENT trial presented at ASCO GU. Participants are invited to listen by dialing (844) 467-7654 (domestic) or (602) 563-8497 (international) five minutes prior to the start of the call and providing the passcode 1085203.

Supporting materials for the conference call and webcast will be available on the Arvinas’ website at www.arvinas.com under Events + Presentations. A replay of the webcast will be archived on the Arvinas website following the presentation.

About Bavdegalutamide (ARV-110)

Bavdegalutamide is an investigational orally bioavailable PROTAC® protein degrader designed to selectively target and degrade the androgen receptor (AR). Bavdegalutamide is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer. Bavdegalutamide has demonstrated activity in preclinical models of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies.

About Arvinas

Arvinas is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies that degrade disease-causing proteins. Arvinas uses its proprietary PROTAC® Discovery Engine platform to engineer proteolysis targeting chimeras, or PROTAC® targeted protein degraders, that are designed to harness the body's own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. In addition to its robust preclinical pipeline of PROTAC® protein degraders against validated and "undruggable" targets, the company has three clinical-stage programs: bavdegalutamide and ARV-766 for the treatment of men with metastatic castration-resistant prostate cancer; and ARV-471 for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. For more information, visit www.arvinas.com.

Arvinas Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of bavdegalutamide, the development and regulatory status of bavdegalutamide and our other product candidates, and the timing of clinical trials and data from those trials and plans for registration for our product candidates, and the potential commercialization of any of our product candidates. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "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.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various risks and uncertainties, including but not limited to: whether we and, as applicable, Pfizer will be able to successfully conduct and complete clinical development for ARV-471, bavdegalutamide, ARV-766 and our other product candidates, including whether we initiate and receive results from our clinical trials on our expected timelines or at all, obtain marketing approval for and commercialize ARV-471, bavdegalutamide, ARV-766 and our other product candidates on our current timelines or at all, and other important factors discussed in the "Risk Factors" sections contained in our quarterly and annual reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this press release reflect our current views with respect to future events, and we assume 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 our views as of any date subsequent to the date of this release.

Arvinas Contacts

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