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 9, 2023

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.

Spokespersons of Arvinas, Inc. (the "Company") plan to present the information in the presentation attached hereto as Exhibit 99.1 (the "Presentation") at various meetings beginning on January 9, 2023, including investor and analyst meetings in connection with the J.P. Morgan 41st Annual Healthcare Conference.

A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Current Report") 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.

By providing the information in Item 7.01 of this Current Report, including Exhibit 99.1 hereto, the Company is not making an admission as to the materiality of any information herein. The information contained in this Current Report is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report, except as may be required by law, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 8.01 Other Events

On January 9, 2023, the Company and Pfizer Inc. ("Pfizer") provided updated guidance related to the anticipated initiation of the VERITAC-3 first-line, metastatic estrogen receptor positive/HER2 negative (ER+/HER2-) breast cancer Phase 3 study of ARV-471 in combination with IBRANCE® (palbociclib).

In the most recent analysis of data from the ongoing Phase 1b combination study of ARV-471 with palbociclib, an increase in palbociclib exposure was observed relative to historical palbociclib pharmacokinetic data.

In light of the recent data analysis, the Company and Pfizer have proposed a modification to the planned VERITAC-3 Phase 3 study and requested a meeting with the U.S. Food and Drug Administration (the "FDA") to review the proposed update to the VERITAC-3 Phase 3 study protocol for ARV-471 in combination with palbociclib to determine the optimal dose of palbociclib as part of the trial design. In the event that the FDA agrees with the proposed amendment, the Company and Pfizer expect to initiate enrollment of the VERITAC-3 Phase 3 study in the second half of 2023. The Company and Pfizer expect to provide a regulatory update after meeting with the FDA.

In the most recent analysis of data from the ongoing Phase 1b study of ARV-471 in combination with palbociclib, the following were observed:

- An approximate increase of 50% in mean palbociclib exposure (i.e., pharmacokinetic area under the curve and Cmax) in the fed state was observed relative to historical palbociclib pharmacokinetic data in the fasted state.
- Grade 3/4 neutropenia, a known dose-related adverse reaction associated with palbociclib, was 76% for 200 mg ARV-471 with 125 mg palbociclib (n=21).
    - As per the U.S. Package Insert, (USPI) the starting dose of palbociclib for patients with HR+/HER2- metastatic breast cancer is 125 mg. As per the palbociclib USPI, a Grade ≥3 decrease in neutrophil counts was reported in 66% of patients receiving IBRANCE plus letrozole in Study 1 (PALOMA-2) and 66% of patients receiving IBRANCE plus fulvestrant in Study 2 (PALOMA-3).
    - There was no increase in the rate of infection reported in the ARV-471 with palbociclib Phase 1b investigation relative to the rates reported in the registrational Phase 3 studies of palbociclib.
- The neutropenia events in the ARV-471 Phase 1b study were manageable with standard dose reductions of palbociclib.
- In the arm combining palbociclib with 200 mg ARV-471, one of 21 patients discontinued.

In addition to the above, the Company also provided the updated guidance set forth below related to its other programs.

- VERITAC-2, a Phase 3 pivotal trial (First Subject First Visit) with ARV-471 as a second-line treatment in patients with ER+/HER2- metastatic breast cancer, is actively recruiting.

- The Company initiated the TACTIVE-U, the Phase 1b trial with ARV-471 in combination with ribociclib and abemaciclib, in two of the combination arms in the fourth quarter of 2022.
- The Company expects to present data from the Phase 1b combination trial of ARV-471 with palbociclib in the second quarter of 2023.
- The Company expects to initiate a Phase 3 trial with ARV-471 in the adjuvant setting.
- The Company expects to initiate a pivotal trial for bavdegalutamide (ARV-110) for the treatment of men with metastatic castration-resistant prostate cancer in the second half of 2023.
- The Company expects to report data from the Phase 1 dose escalation trial of ARV-766 for the treatment of men with metastatic castration-resistant prostate cancer in the second quarter of 2023.
- The Company expects to submit an investigational new drug ("IND") application or clinical trial application ("CTA") for its BCL6 PROTAC® degrader in the second half of 2023.
- The Company expects to submit an IND or CTA for its PROTAC® LRRK2 degrader in the second half of 2023.
- The Company expects to have two additional programs in IND-enabling studies by the end of 2023.

Forward-Looking Statements

This Current Report contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the proposed amendment to the VERITAC-3 Phase 3 study protocol, the timelines related to the initiation of such study; the anticipated initiation, data read out and/or IND/CTA filing timelines associated with monotherapy and combination studies of ARV-471, the bavdegalutamide (ARV-110) pivotal trial, ARV-766 Phase 1 trial, and LRRK2 and BCL6 clinical candidates. All statements, other than statements of historical facts, contained in this Current Report, 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 the Company's forward-looking statements, and you should not place undue reliance on the Company's 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: the Company's and Pfizer's performance of their respective obligations with respect to the Company's collaboration with Pfizer; whether the Company and Pfizer will be able to successfully conduct and complete clinical development for ARV-471; whether the Company obtains marketing approval for and commercialize ARV-471 on its current timelines or at all; whether the Company's 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent other reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this Current Report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Company Presentation, dated January 9, 2023.
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 9, 2023

By: /s/ Sean Cassidy

Sean Cassidy
Chief Financial Officer

ARVINAS

J.P. Morgan Healthcare Conference

January 11, 2023

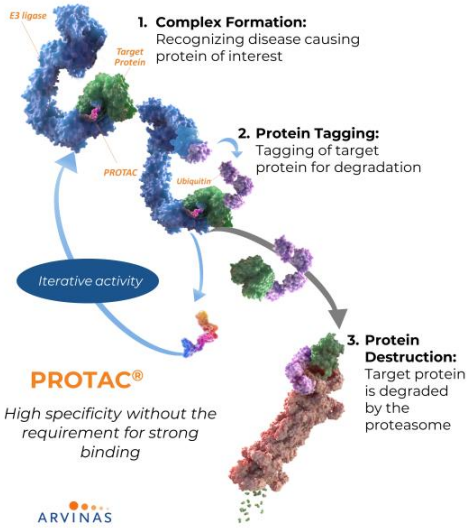
Safe harbor and forward-looking statements

This presentation 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 anticipated timing of our planned clinical trials within our pipeline, including VERITAC-3, a trial of ARV-471 in combination with palbociclib, our ARV-471 monotherapy study in the adjuvant setting, and our bavdegalutamide (ARV-110) monotherapy study; the potential therapeutic benefits of ARV-471; the expected timing for submission of investigational new drug applications or clinical trial authorization applications for our preclinical candidates as well as timing of initiation of two additional enabling studies for our preclinical candidates; whether our preclinical programs will help treat patients with solid and haematological cancerous malignancies and neurodegenerative disorders; whether ARV-471's tolerability and signals of efficacy could allow its potential use as a "backbone" of care across stages of breast cancer; whether our PROTAC® degraders eliminating the androgen receptor, or AR, may surpass the benefits of AR inhibitors and the extent to which an AR-targeting PROTAC® degrader may address the unmet needs of patients with prostate cancer across multiple stages of disease; the timing for beginning a pivotal trial for bavdegalutamide and AR PROTAC® investigations in pre- and post-novel hormonal agent settings; whether our BCL6 PROTAC® degrader will be a first-in-class potential therapy for Diffuse Large B-Cell Lymphoma; and the timing of clinical trial initiations, including pivotal trials, first in human studies of PROTAC® protein degraders and certain data readouts. 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 Pfizer will be able to successfully conduct clinical development for ARV-471 and receive results from our clinical trials on our expected timelines, or at all; whether we will be able to successfully conduct and complete development for bavdegalutamide (ARV-110), ARV-766, and our other product candidates, including whether we initiate and complete clinical trials for our product candidates and receive results from our clinical trials on our expected timelines, or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of our quarterly and annual reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this presentation reflect our current views as of the date of this presentation 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 presentation.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. This presentation is intended for the investor community only. It is not intended to promote the products referenced herein or otherwise influence healthcare prescribing decisions. Cross-trial comparisons are not based on head-to-head studies and no direct comparisons can be made.

PROTAC® protein degraders combine the benefits of small molecules and gene-based knockdown technologies



Arvinas' proteolysis-targeting chimera (PROTAC®) degraders can:

- Eliminate (rather than inhibit) disease-causing proteins
- Disrupt scaffolding functions of target proteins
- Bind and degrade classically "undruggable" proteins
- Act iteratively (catalytically)
- Be delivered orally and achieve broad tissue distribution, including across the blood-brain-barrier

Leaders in a new class of novel treatments

Consistent ability to create PROTAC® degraders with drug-like properties and signals of clinical efficacy and tolerability

One program in a Phase 3 study, and **two** drug candidates in **Phase 2**

Creating **potential therapies for patients** in both **oncology** and **neuroscience**

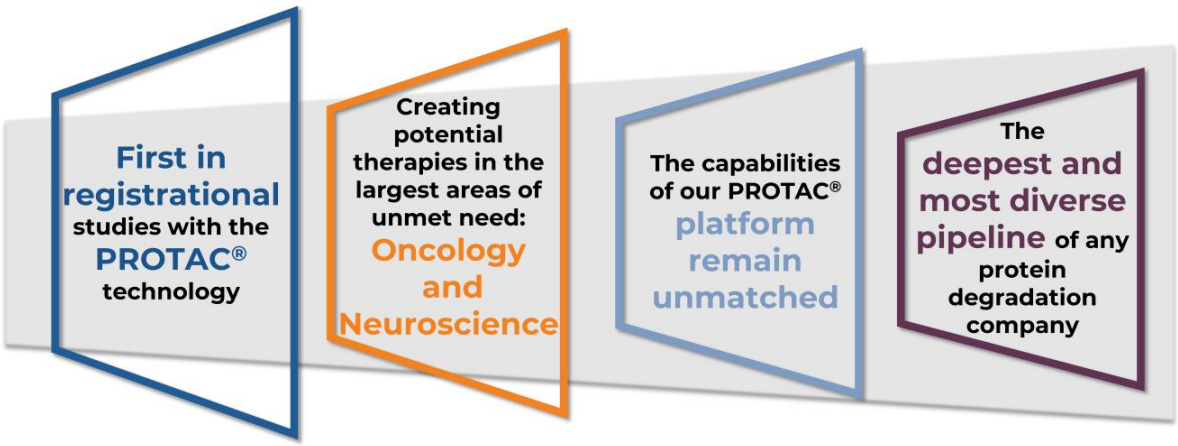
~$1.3B cash on-hand[1]

Partnerships with global leaders in drug discovery, development, and commercialization

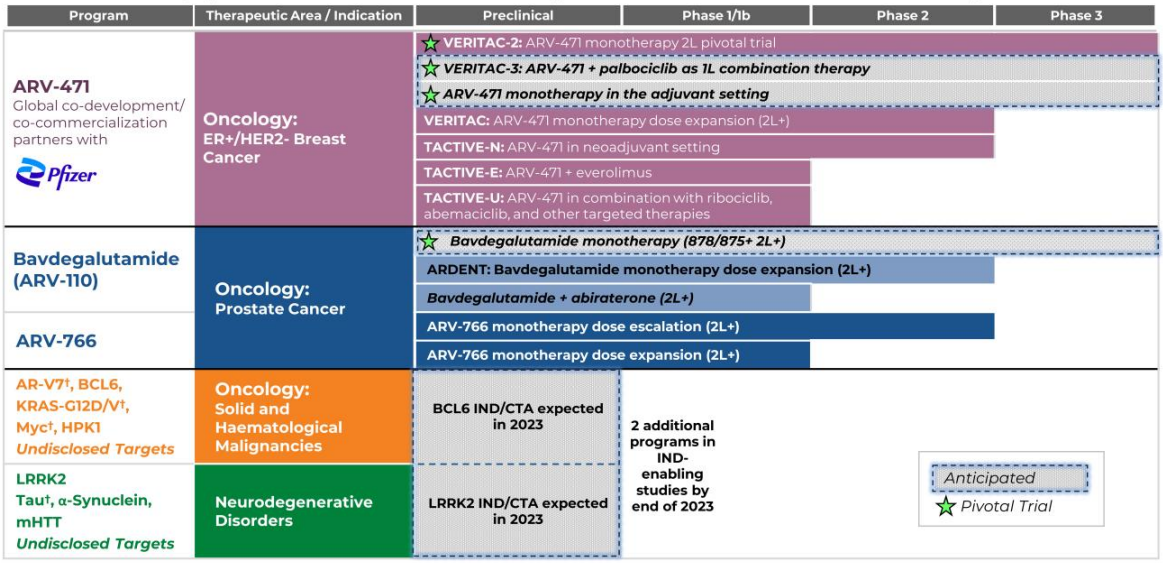
Pfizer · Genentech · Gerthbio · Bayer · GNS · Insilico Medicine · PHOREMOST

[1] Cash, cash equivalents, and marketable securities as of September 30, 2022

Building a unique protein degradation company



Our broad pipeline includes the first pivotal trials for PROTAC® degraders



These agents are currently under investigation. Their safety and effectiveness for these investigational uses have not yet been established.
IND, investigational new drug; CTA, clinical trial application
† Denotes historically undruggable proteins

ARV-471: First-in-class Estrogen Receptor (ER)-degrading PROTAC® in advanced breast cancer

1 in 8 U.S. women will develop breast cancer in her lifetime†

~80% of all newly diagnosed cases of breast cancer are ER-positive (ER+)††

ARV-471 has the potential to become an oral, best-in-class targeted therapy

- Fulvestrant is a successful standard of care, but has limitations; resistance is a challenge
- Preclinically, ARV-471 demonstrated superior ER degradation (>90%) and superior tumor regression versus fulvestrant
- ARV-471 is a potent degrader of ER as well as a complete ER antagonist

Very promising efficacy and tolerability profile to date

ER, estrogen receptor
† ACS: https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html; accessed 01/06/23
†† https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4549764/, accessed 1/4/2023

ARV-471: Excellent tolerability and signals of efficacy in the most heavily pretreated patients of any ER-targeting therapy

ARV-471 Phase 2 Patients *Prior Treatment:*	Prior CDK4/6i **100%**	Prior Fulvestrant **79%**	Prior Metastatic Chemo **45%**
ARV-471 demonstrated strong signals of efficacy in the VERITAC Phase 2 trial	**Clinical Benefit Rate** (Phase 2):	**38%** (All patients) **51%** (Patients with ESR1 mutant tumors)	
	Progression-Free Survival (Phase 2):	**3.7 Months** (All patients) **5.7 Months** (Patients with ESR1 mutant tumors)	
ARV-471 has been well tolerated	Grade 3/4 TRAE reported in 6% (2/35) patients at 200 mg		
	In 35 patients treated at the recommended Phase 3 dose (200 mg), **no dose reduction and 1 discontinuation**		

ESR1, Estrogen Receptor 1
Clinical benefit rate defined as rate of confirmed complete response or partial response or stable disease ≥24 weeks

Data as presented 2022

Our VERITAC-2[1] Phase 3 pivotal trial is designed for success

Treatment (N = 560)

Randomize 1:1

- **ARV-471** 200 mg orally once daily
- **Fulvestrant** 500 mg intramuscularly

Days 1 and 15 of cycle 1 and Day 1 of subsequent cycle

Select Patient Eligibility Criteria

- Prior CDK4/6 inhibitor treatment
- No prior fulvestrant
- No prior chemotherapy for locally advanced / metastatic disease

Primary Endpoints

Progression Free Survival (PFS) by Blinded Independent Central Review in:

- ESR1 mutant population
- All Comers (Intention To Treat) population

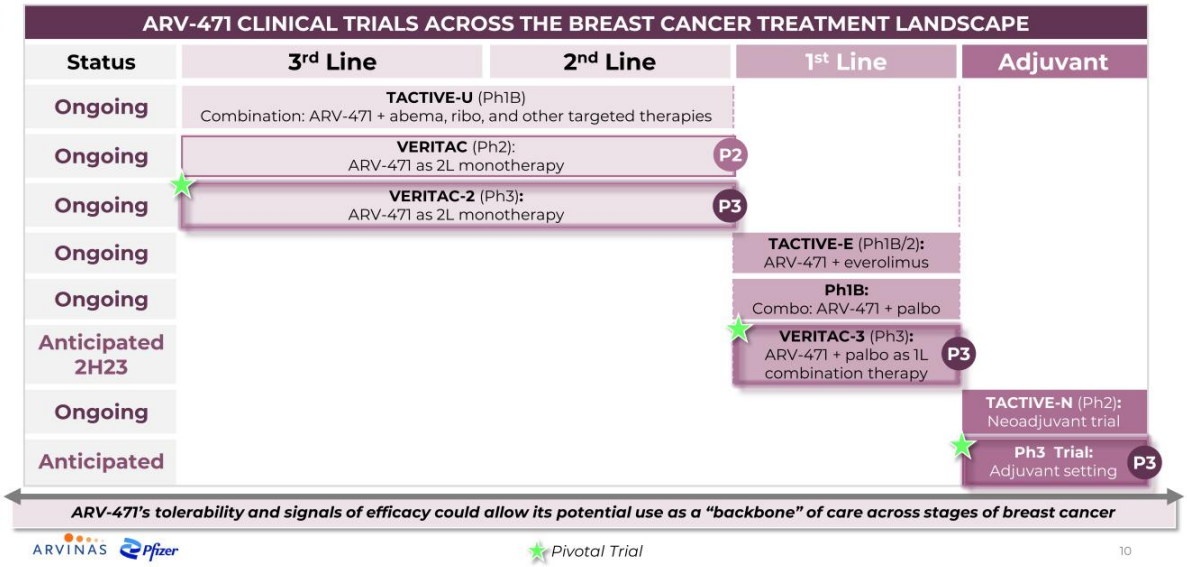
- In CDK4/6 inhibitor-pretreated patients, ER therapies appear to have **greater activity in ESR1 mutant tumors**
- **ARV-471 degrades ESR1mut and ESR1wt equally**, and has already demonstrated signals of **efficacy in both *ESR1* mutant and wild-type patients**
- **VERITAC-2 will enroll less-pretreated, more ER-driven, 2L patients** (vs. the VERITAC Ph 2 trial)
  - In the VERITAC Ph 2 trial, less-pretreated 2L patients[2] had a numerically higher clinical benefit rate

ESR1, estrogen receptor 1; ESR1mut, ESR1 mutant; ESR1wt, ESR1 wild type

[1] NCT05654623

[2] Patients without prior fulvestrant or chemotherapy for advanced disease

With Pfizer, we are building a robust ARV-471 development program to impact multiple settings of breast cancer



ARVINAS Pfizer

Pivotal Trial

Arvinas' PROTAC® degraders eliminate the androgen receptor (AR), potentially surpassing the benefits of AR inhibitors

1 in 8 U.S. men will be diagnosed with prostate cancer during their lifetime[1]

Prostate cancer is the **2nd leading cause of cancer death** for men in the U.S.[2]

An AR-targeting PROTAC degrader may address the unmet needs of patients with prostate cancer across multiple stages of disease

AR is a critical target in prostate cancer, but tumors develop resistance to standard-of-care AR inhibitors

Arvinas has two oral AR-targeting PROTAC degraders in Phase 2 studies:

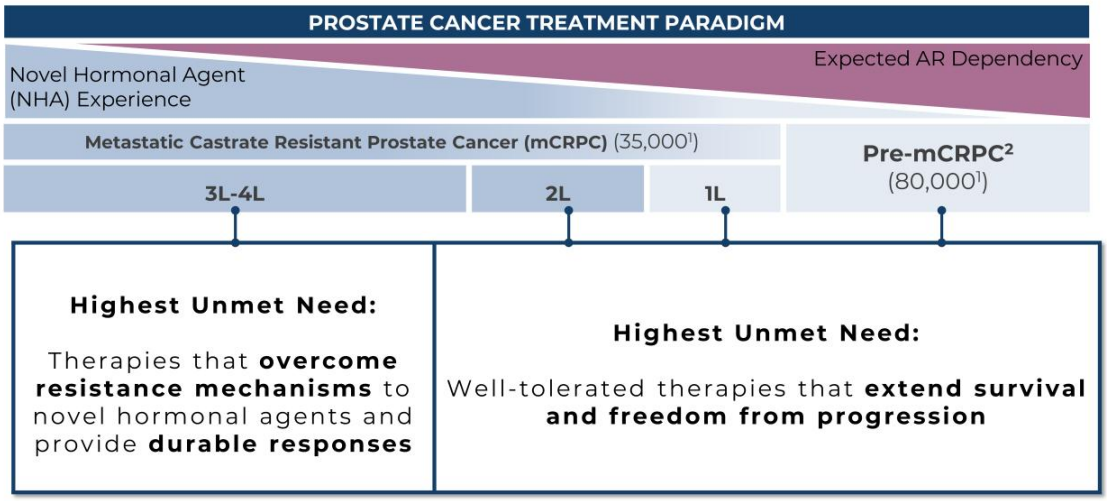
- Bavdegalutamide (ARV-110)
- ARV-766

Activity in late-line settings suggests potential for even stronger benefit in earlier-line, less-pretreated patients

AR, androgen receptor

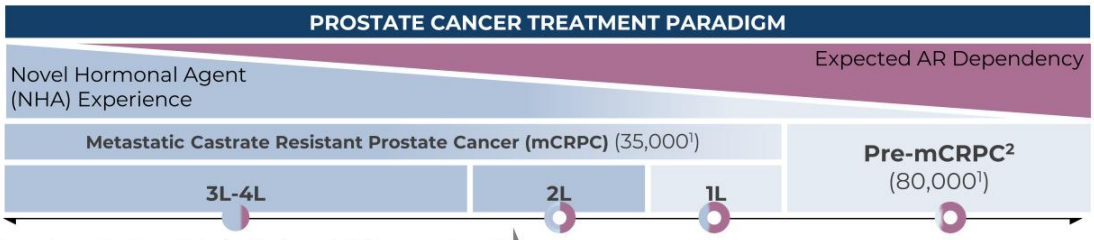
[1] ACS: https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html, accessed 2/22/22;
[2] American Cancer Society

Arvinas' PROTAC® degraders could meet the substantial unmet need across the prostate cancer treatment paradigm



[1] Decision Resources Group – Diagnosed Patients
[2] Includes Castrate Sensitive Prostate Cancer, Biochemical / Recurrent Prostate Cancer, and non-mCRPC

In late-line mCRPC, bavdegalutamide has shown compelling signals of efficacy and manageable tolerability



Bavdegalutamide's tolerability and compelling signals of efficacy in this late-line, highly refractory setting…

In Phase 2, bavdegalutamide demonstrated:

- *46% PSA_{50} response rate in patients with AR T878X/H875Y-positive tumors*
- *0% Grade ≥4 TRAEs*
- *Low rates of discontinuation and dose reduction*

Data as presented at ASCO Genitourinary Cancers Symposium **2022**

…suggest the strong potential for patient benefit in earlier settings

- *Post-NHA, T878X/H875Y mutations are believed to be markers of AR dependence*
- *In pre-NHA settings, most patients expected to be AR-driven*

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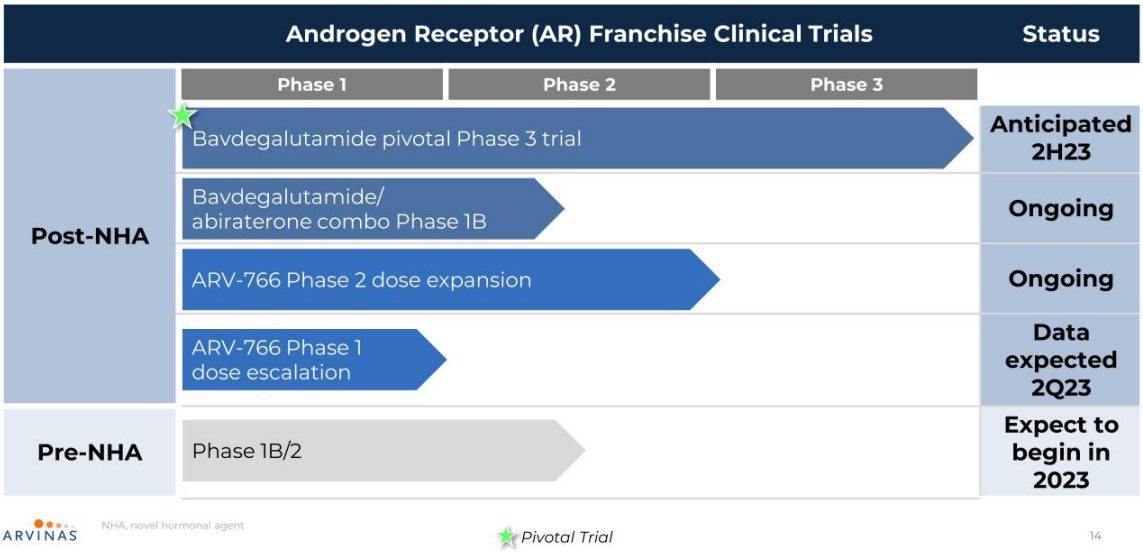
NHA, novel hormonal agent; TRAE, treatment-related adverse event
[1] Decision Resources Group – Diagnosed Patients
[2] Includes Castrate Sensitive Prostate Cancer, Biochemical / Recurrent Prostate Cancer, and non-mCRPC

In 2023, we expect to begin a pivotal trial for bavdegalutamide and to begin AR PROTAC® investigations in pre-NHA settings



ARVINAS NHA, novel hormonal agent

Pivotal Trial

Industry leading preclinical pipeline of degraders

*Arvinas' pipeline is **differentiated and sustainable***

***20+** Pre-clinical programs across oncology and neurodegenerative disease*

***4** first-in-human studies of new PROTAC® programs beginning in the next 24 months*

The capabilities of our PROTAC® platform remain unmatched

The deepest and most diverse pipeline of any protein degradation company

We expect our BCL6 PROTAC® degrader to be a first-in-class potential therapy for Diffuse Large B-Cell Lymphoma (DLBCL)

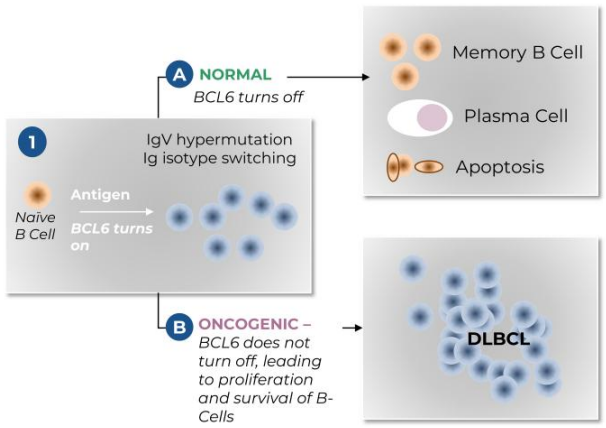
BCL6 is genetically mutated in up to 85% of DLBCL[1], a subset of Non-Hodgkin's Lymphoma

More than 18,000 people are diagnosed with DLBCL each year[2]

DLBCL is largely devoid of oral options; there is no BCL6-targeted therapy on the market or in the clinic

Additional opportunities for a BCL6 degrader exist in Burkitt's Lymphoma, Follicular Lymphoma, Angioimmunoblastic T-cell lymphoma, and solid tumors

The role of BCL6 in driving DLBCL[3]



DLBCL, diffuse large B cell lymphoma; Ig, immunoglobulin
[1] Iqba et. al., 2007
[2] Lymphoma Foundation, bit.ly/3jAnJ1S;
[3] Figure adapted from Pasqualucci et. al., 2003 (figure at bit.ly/3QBICHH)

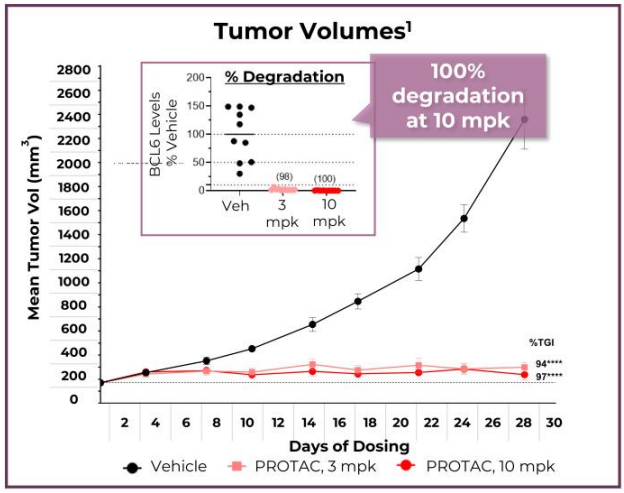
Our oral, BCL6-targeting PROTAC® clinical candidate inhibits tumor growth by nearly 100% in preclinical models

Complete tumor stasis at low, oral daily doses

Tumor stasis correlates with 95-100% degradation of measurable BCL6

Similar activity in multiple DLBCL models, including for activated B cell and germinal center B cell lymphomas

Program is currently in GLP toxicity studies; IND/CTA expected in 2H23



DLBCL, Diffuse Large B-Cell Lymphoma; IND, investigational new drug application; CTA, clinical trial application; mpk, milligrams per kilogram
[1] Model: OCI-Ly1. Dosing is oral, twice daily

PROTAC® degraders could revolutionize the treatment of patients with neurological diseases

We are creating PROTAC® degraders that can:

- ✓ **Cross the blood-brain barrier**
- ✓ **Reach targets in "deep brain" regions**
- ✓ **Degrade disease-causing proteins inside cells**
- ✓ **Differentiate between mutant and wild-type proteins, e.g., mutant huntingtin**
- ✓ **Be delivered orally**

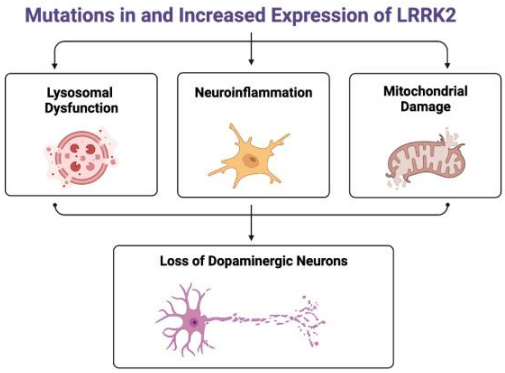
Significant potential advantages over existing modalities

ARVINAS

PROTAC®-induced LRRK2 degradation could be a disease-modifying modality for Parkinson's Disease

LRRK2 is a multidomain scaffolding kinase that contributes to PD (familial and idiopathic)

- Parkinson's Disease (PD) is the second most common neurodegenerative disease, with a diagnosed prevalence of 2.5M in the US, EU5, and Japan
- No disease-modifying therapies have been approved for PD
- Familial mutations and sporadic variants (~2x increase in expression) implicate leucine-rich repeat kinase 2 (LRRK2) in PD
- Human genetics and preclinical animal model data suggest that reduction of 50% of LRRK2 protein, but not kinase inhibition, may impact pathology and dysfunction in PD[1]



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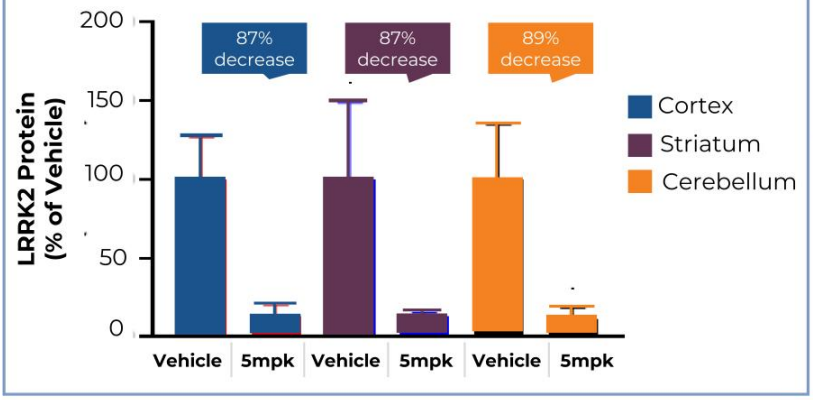
LRRK2, leucine-rich repeat kinase 2; PD, Parkinson's Disease
[1] Wang, 2021, Zhao, 2017, Henderson, 2019

Our oral PROTAC® clinical candidate reaches multiple "deep brain" regions in non-human primates and degrades LRRK2

>85% LRRK2 degradation in deep brain regions of cynomolgus monkeys after oral dosing



Program currently in GLP toxicity studies

IND/CTA expected in 2H23

CTA, clinical trial application; GLP, good laboratory practice; IND, investigational new drug application; LRRK2, leucine-rich repeat kinase 2; mpk, milligrams per kilogram

Data as presented at SfN 2022

In the next 24 months:

4
PIVOTAL TRIALS
expected to be ongoing in breast and prostate cancer

5+ clinical trial data readouts expected, including topline data for **1 Pivotal** Trial

4 first-in-human studies of new PROTAC® programs anticipated across oncology and neuroscience

Thank You

For More Information

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