



Arvinas Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

February 11, 2025

– Announced that topline data from the monotherapy Phase 3 VERITAC-2 trial is anticipated in 1Q25 –

– Presented Phase 1b data from the TACTIVE-U sub-study of vepdegestrant in combination with abemaciclib that demonstrated encouraging clinical activity (clinical benefit rate: 62.5%; overall response rate: 26.7%) in patients previously treated with a CDK4/6 inhibitor –

– Announced the planned initiation of first-line Phase 3 trial evaluating vepdegestrant in combination with Pfizer's novel investigational CDK4 inhibitor atirmociclib and a second-line Phase 3 combination trial evaluating vepdegestrant with a CDK4/6 inhibitor, both planned to begin in 2025 –

– Initiated a Phase 1 trial with ARV-102 in patients with Parkinson's disease and announced Phase 1 data in healthy volunteers has been accepted for oral presentation at Alzheimer's Disease/Parkinson's Disease congress –

– Company to host conference call today at 8:00 a.m. ET –

NEW HAVEN, Conn., Feb. 11, 2025 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided a corporate update.

"We made significant progress across our pipeline in 2024, all of which we believe supports our mission to improve the lives of patients with debilitating and life-threatening diseases," said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. "Looking ahead, we are on the cusp of a number of firsts, including results from VERITAC-2, the first ever Phase 3 clinical trial of a PROTAC. In addition, we plan to present the first-in-human data for our most advanced neuroscience program, ARV-102, which we believe will highlight the potential value our PROTAC degraders can offer to patients with neurodegenerative diseases. In the coming months, we look forward to sharing additional updates emerging from our pipeline and PROTAC platform."

4Q 2024 Business Highlights and Recent Developments

Vepdegestrant: Oral PROTAC ER degrader

- Announced that the VERITAC-2 Phase 3 monotherapy clinical trial evaluating vepdegestrant in ER+/HER2- metastatic breast cancer remains on track, with topline data anticipated in 1Q25 (ClinicalTrials.gov Identifier: NCT05654623).
- Announced plans to initiate two new Phase 3 combination trials in patients with ER+/HER2- mBC (pending emerging data and regulatory feedback) in 2025:
 - 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.
- Presented initial Phase 1b safety and pharmacokinetic data from the TACTIVE-U sub-study of vepdegestrant in combination with abemaciclib at the San Antonio Breast Cancer Symposium (SABCS) in December 2024 (ClinicalTrials.gov Identifier: NCT05548127).
- Presented data from the Phase 1 clinical pharmacology study of vepdegestrant in combination with midazolam at SABCS in December 2024 (ClinicalTrials.gov Identifier: NCT06256510).
- Continued enrollment globally in multiple additional clinical studies of vepdegestrant in ER+/HER2- metastatic breast cancer.
 - TACTIVE-K: Phase 1b/2 clinical trial with vepdegestrant in combination with Pfizer's novel investigational CDK4 inhibitor atirmociclib (ClinicalTrials.gov Identifier: NCT06206837).
 - TACTIVE-U: Phase 1b/2 combination umbrella trial evaluating combinations of vepdegestrant with abemaciclib, ribociclib, or samuraciclib (ClinicalTrials.gov Identifiers: NCT05573555, and NCT06125522).

ARV-393: Oral PROTAC BCL6 degrader

- Continued recruiting patients in the first-in-human Phase 1 clinical trial in patients with non-Hodgkin lymphoma (NHL) (ClinicalTrials.gov Identifier: NCT06393738).

ARV-102: Oral PROTAC LRRK2 degrader

- Completed enrollment in the multiple ascending (MAD) dose cohort of the Phase 1 clinical trial in healthy volunteers in 1Q25.
- Initiated dosing of the first patients with Parkinson's disease (PD) in the single ascending dose (SAD) cohort of a Phase 1 clinical trial.

Corporate

- Completed the Investigational New Drug application (IND) transition of luxdegalutamide (ARV-766) to Novartis as part of global license agreement executed in April 2024.
- Announced Alex Santini, Arvinas' Senior Vice President, Global and U.S. Market Access, has been appointed interim Chief Commercial Officer effective January 17, 2025.

Anticipated Upcoming Milestones and Expectations

Vepdegestrant: Oral PROTAC ER degrader

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

- Announce topline data for the VERITAC-2 Phase 3 monotherapy clinical trial evaluating vepdegestrant in patients with ER+/HER2- metastatic breast cancer (mBC) in a topline press release 1Q25 and present full results of the trial at a medical conference in 2025.
- Initiate two new Phase 3 combination trials in patients with ER+/HER2- mBC (pending emerging data and regulatory feedback) in 2025:
 - 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 Phase 3 clinical trial evaluating vepdegestrant plus palbociclib in the first-line will not proceed beyond the study lead-in.
- Continue to collect safety and efficacy data from ongoing TACTIVE-U sub-studies evaluating combination of vepdegestrant with abemaciclib, ribociclib, or samuraciclib (ClinicalTrials.gov Identifiers: NCT05548127, NCT05573555, and NCT06125522) and submit key data for presentation at medical conference.
- Continue enrollment in the Phase 2 TACTIVE-K clinical trial (atirmociclib + vepdegestrant) and submit initial Phase 1b data for presentation at a medical conference.

ARV-393: Oral PROTAC BCL6 degrader

- Present preclinical data of ARV-393 in combination with standard of care biologic agents and small molecule inhibitors in high grade and aggressive diffuse large B-cell lymphoma *in vivo* models at the American Association for Cancer Research Annual Meeting (April 25-30, 2025).
- Disclose preliminary data from the ongoing Phase 1 clinical trial in patients with NHL (ClinicalTrials.gov Identifier: NCT06393738) in 2025.

ARV-102: Oral PROTAC LRRK2 degrader

- Present SAD 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) demonstrating:
 - Bioavailability and brain penetration with dose dependent exposure in cerebral spinal fluid (CSF)
 - Degradation of LRRK2 in the periphery and CSF of healthy volunteers
- Complete enrollment and present initial data from the ongoing SAD Phase 1 clinical trial in patients with PD in 2025; initiate MAD cohort in patients with PD in 2025.

Novel PROTAC KRAS G12D degrader

- File an Investigational New Drug (IND) application in 2025.

Financial Guidance

Based on its current operating plan, Arvinas believes its cash, cash equivalents, and marketable securities as of December 31, 2024, is sufficient to fund planned operating expenses and capital expenditure requirements into 2027.

Full Year and Fourth Quarter Financial Results

Cash, Cash Equivalents, and Marketable Securities Position: As of December 31, 2024, cash, cash equivalents and marketable securities were \$1,039.4 million as compared with cash, cash equivalents, restricted cash and marketable securities of \$1,266.5 million as of December 31, 2023. The decrease in cash, cash equivalents and marketable securities of \$227.1 million for

the 12 months ended December 31, 2024 was primarily related to cash used in operations of \$237.4 million (net of \$150.0 million received from the Novartis agreements), inclusive of a one-time cash termination fee in the amount of \$41.5 million related to the termination of our laboratory and office space lease with 101 College Street LLC in August 2024, the purchase of lab equipment and leasehold improvements of \$1.8 million and \$0.4 million of long term debt repayments, partially offset by proceeds from the exercise of stock options of \$8.3 million, unrealized gains on marketable securities of \$4.1 million and proceeds from disposal of equipment of \$0.1 million.

Research and Development Expenses: Research and development expenses were \$348.2 million and \$83.3 million for the year and quarter ended December 31, 2024, respectively, as compared with \$379.7 million and \$95.2 million for the year and quarter ended December 31, 2023, respectively. The decrease in research and development expenses of \$31.5 million for the year was primarily due to a decrease in external expenses of \$41.7 million, partially offset by an increase in compensation and related personnel expenses of \$11.2 million, which are not allocated by program. External expenses include program-specific expenses, which decreased by \$32.1 million, driven by decreases in our vepdegestrant and bavdegalutamide (ARV-110) programs of \$27.9 million and \$18.1 million, respectively, partially offset by increases in our ARV-102 and ARV-393 programs of \$10.7 million and \$5.4 million, respectively, and our non-program specific expenses, which decreased by \$9.6 million. The decrease in research and development expenses of \$11.9 million for the quarter was primarily due to a decrease in external expenses of \$9.9 million, compensation and related personnel expenses of \$0.5 million, which are not allocated by program, and other expenses of \$1.5 million. External expenses include program-specific expenses, which decreased by \$14.2 million, primarily driven by decreases in our vepdegestrant, luxdegalutamide (ARV-766) and bavdegalutamide (ARV-110) programs of \$13.6 million, \$6.0 million and \$2.6 million, respectively, partially offset by increases in our ARV-102 and ARV-393 programs of \$5.5 million and \$1.3 million, respectively, and our non-program specific expenses of \$4.3 million.

General and Administrative Expenses: General and administrative expenses were \$165.4 million and \$34.1 million for the year and quarter ended of December 31, 2024, respectively, as compared with \$100.3 million and \$27.0 million for the year and quarter ended of December 31, 2023, respectively. The increase in general and administrative expenses of \$65.1 million for the year was primarily due to a loss on the termination of our laboratory and office space lease with 101 College Street LLC in August 2024 of \$43.4 million as well as increases in personnel and infrastructure related costs of \$9.0 million, professional fees of \$8.1 million and in developing our commercial operations of \$4.2 million. The increase in general and administrative expenses of \$7.1 million for the quarter was primarily due to increases in developing our commercial operations of \$2.6 million, personnel and infrastructure related costs of \$2.2 million and professional fees of \$1.8 million.

Revenue: Revenue was \$263.4 million and \$59.2 million for the year and quarter ended December 31, 2024, respectively, as compared with \$78.5 million and \$(43.1) million for the year and quarter ended December 31, 2023, respectively. The increase in revenue of \$184.9 million for the year was primarily due to revenue from the Novartis agreements of \$162.4 million, an increase in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer of \$21.7 million related in part to adjustments to revenue in 2023 from changes in contract estimates and year over year increases in revenue of \$2.8 million and \$2.2 million from the Bayer Collaboration Agreement and the Pfizer Research Collaboration Agreement, respectively, primarily due to changes in estimates in 2023 of the performance period duration under the agreements resulting from updated research timelines, offset by a decrease of \$2.5 million of previously constrained deferred revenue related to our Oerth Bio joint venture, and a decrease of \$1.8 million of revenue under the Restated Genentech Agreement as the performance period had concluded in 2023. The increase in revenue of \$102.3 million for the quarter was primarily related to an increase in revenue from the Pfizer ARV-471 Collaboration Agreement totaling \$63.8 million, primarily due to adjustments in 2023 to revenue from changes in contract estimates, as well as revenue from the Novartis agreements of \$40.3 million, offset by a decrease in revenue from Bayer of \$1.6 million related to the termination of the Bayer Collaboration Agreement in August 2024.

Investor Call & Webcast Details

Arvinas will host a conference call and webcast today, February 11, 2025, at 8:00 a.m. ET to review its fourth quarter and full year 2024 financial results and discuss recent corporate updates. Participants are invited to listen by going to the Events and Presentation section under the Investors page on the Arvinas website at www.arvinas.com. A replay of the webcast will be available on the Arvinas website following the completion of the event and will be archived for up to 30 days.

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, Arvinas 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 progress made across Arvinas' pipeline in 2024 supporting Arvinas' mission to improve the lives of patients with debilitating and life-threatening diseases; the expected timing in connection with the reporting of topline data from the VERITAC-2 Phase 3 clinical trial and presentation of full results at a medical congress; the plans to present the first-in-human data for ARV-102 and the presentation of such data highlighting the potential value Arvinas' PROTAC degraders can offer to patients with neurodegenerative diseases; the plans related to the initiation of two Phase 3 vepdegestrant combination trials, in the first- and second-line settings, and the timing thereof; plans to continue to collect safety and efficacy data from ongoing TACTIVE-U sub-studies and submit key data from TACTIVE-U for presentation at a medical conference; plans to continue enrollment in the Phase 2 TACTIVE-K clinical trial and submit initial Phase 1b data from TACTIVE-K for presentation at a medical conference; plans to present preclinical data of ARV-393 in combination with standard of care biologic agents and small molecule inhibitors in high grade and aggressive DLBCL *in vivo* models; plans to present single ascending dose ("SAD") data from the ongoing Phase 1 clinical trial of ARV-102 in healthy volunteers; plans to complete enrollment and present initial data from the ongoing SAD Phase 1 clinical trial of ARV-102 in patients with Parkinson's disease ("PD") and initiate a multiple ascending dose cohort in patients with PD; plans to file an Investigational New Drug application for a novel KRAS G12D PROTAC degrader and the timing thereof; vepdegestrant's development as a potential monotherapy and as part of combination therapy across multiple treatment settings for estrogen receptor positive, human epidermal growth factor receptor 2 negative metastatic breast cancer; and statements regarding Arvinas' cash, cash equivalents and marketable securities, including their sufficiency to fund planned operating expenses and capital expenditure requirements into 2027. 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: whether Arvinas and Pfizer will successfully perform their respective obligations under the collaboration between Arvinas and 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 ARV-393 and ARV-102, and including whether Arvinas initiates and completes clinical trials for its product candidates and receives results from its clinical trials and preclinical studies on its expected timelines or at all; whether Arvinas and Pfizer, as appropriate, will be able to obtain marketing approval for and commercialize vepdegestrant and other product candidates on current timelines or at all; Arvinas' ability to protect its intellectual property portfolio; Arvinas' reliance on third parties; whether Arvinas will be able to raise capital when needed; 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 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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	December 31,	
	2024	2023
<i>(dollars and shares in millions, except per share amounts)</i>		
Assets		
Current assets:		
Cash and cash equivalents	\$ 100.5	\$ 311.7
Restricted cash	—	5.5
Marketable securities	938.9	949.3
Accounts receivable	5.7	—
Other receivables	8.0	7.2
Prepaid expenses and other current assets	14.2	6.5
Total current assets	1,067.3	1,280.2
Property, equipment and leasehold improvements, net	7.0	11.5
Operating lease right of use assets	9.0	2.5
Collaboration contract asset and other assets	8.1	10.4
Total assets	\$ 1,091.4	\$ 1,304.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 71.8	\$ 92.2
Deferred revenue	156.2	163.0
Current portion of operating lease liability	1.8	1.9
Total current liabilities	229.8	257.1
Deferred revenue	292.0	386.2
Long term debt	0.6	0.8
Operating lease liability	7.3	0.5
Total liabilities	529.7	644.6
Stockholders' equity:		
Preferred stock, \$0.001 par value, zero shares issued and outstanding as of December 31, 2024 and 2023, respectively	—	—
Common stock, \$0.001 par value, 68.8 and 68.0 shares issued and outstanding as of December 31, 2024 and 2023, respectively	0.1	0.1
Accumulated deficit	(1,531.6)	(1,332.7)
Additional paid-in capital	2,092.2	1,995.7
Accumulated other comprehensive income (loss)	1.0	(3.1)
Total stockholders' equity	561.7	660.0
Total liabilities and stockholders' equity	\$ 1,091.4	\$ 1,304.6

ARVINAS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
<i>(dollars and shares in millions, except per share amounts)</i>				
Revenue	\$ 59.2	\$ (43.1)	\$ 263.4	\$ 78.5
Operating expenses:				
Research and development	83.3	95.2	348.2	379.7
General and administrative	34.1	27.0	165.4	100.3
Total operating expenses	117.4	122.2	513.6	480.0
Loss from operations	(58.2)	(165.2)	(250.2)	(401.5)
Interest and other income	12.7	12.1	51.9	37.6
Net loss before income taxes and loss from equity method investment	(45.5)	(153.2)	(198.3)	(363.9)
Income tax benefit (expense)	0.4	(1.6)	(0.6)	(0.9)

Loss from equity method investment	—	—	—	(2.5)
Net loss	\$ (45.1)	\$ (154.8)	\$ (198.9)	\$ (367.3)
Net loss per common share - basic and diluted	\$ (0.63)	\$ (2.53)	\$ (2.77)	\$ (6.62)
Weighted average common shares outstanding - basic and diluted	72.1	61.1	71.9	55.5