Arvinas Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

February 28, 2022

NEW HAVEN, Conn., Feb. 28, 2022 (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, 2021 and provided a corporate update.

“It has been an exciting time for Arvinas over the past 12 months, including the beginning of a transformational collaboration with Pfizer, and compelling clinical updates supporting our two lead clinical programs, ARV-471 and bavdegalutamide, or ARV-110,” said John Houston, Ph.D., chief executive officer and president at Arvinas. “We believe ARV-471 has the potential for a best-in-class profile for the treatment of ER+/HER2- breast cancer and, looking ahead, we have a number of important clinical milestones upcoming with ARV-471, including the initiation of two planned Phase 3 trials in metastatic breast cancer as a monotherapy and in combination.”

“To follow up our strong finish to 2021, we began 2022 by presenting new data at ASCO GU that showed bavdegalutamide demonstrated a clinical profile that we believe supports its potential as a precision medicine for men with prostate cancer and tumors harboring AR T878/H875 point mutations,” continued Dr. Houston. “We anticipate starting a pivotal trial with bavdegalutamide by year-end 2022, which will be our third pivotal trial planned for the year – one with bavdegalutamide, and two with ARV-471. We are making significant progress across our pipeline, bringing us one step closer to potentially delivering life-saving new therapies to patients.”

Business Highlights and Recent Developments

- In December 2021, presented ARV-471 Phase 1 dose escalation trial data at the San Antonio Breast Cancer Symposium, continuing to demonstrate an encouraging clinical benefit rate (CBR) in patients with locally advanced or metastatic ER+/HER2- breast cancer
    - ARV-471 demonstrated antitumor activity in patients previously treated with cyclin-dependent kinase (CDK) 4/6 inhibitors, with a CBR of 40% in 47 evaluable patients
    - Three patients exhibited confirmed RECIST (Response Evaluation Criteria in Solid Tumors) partial responses (among 38 patients with measurable disease at baseline who had ≥1 on-treatment scan)
    - ARV-471 continued to demonstrate a favorable tolerability profile
- In February 2022, presented completed Phase 1 dose escalation and ongoing Phase 2 ARDENT expansion cohort data from bavdegalutamide in metastatic castration-resistant prostate cancer (mCRPC) at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), that showed:
    - A PSA_{50} rate (reduced prostate-specific antigen (PSA) levels greater than or equal to 50%) of 46% in patients with AR T878X/H875Y (T878X = T878A or T878S) tumor mutations (n=28)
    - Two durable confirmed RECIST partial responses (out of seven RECIST-evaluable patients with AR T878X/H875Y tumor mutations)
    - Bavdegalutamide had a manageable tolerability profile at the recommended Phase 2 dose (RP2D) of 420 mg oral, once daily
    - PSA reductions and evidence of anti-tumor activity as measured by RECIST were observed across all subgroups regardless of mutation status, including in patients with tumors not harboring AR T878X/875Y mutations

Anticipated 2022 Milestones and Expectations

ARV-471

- Present data from the VERITAC Phase 2 expansion trial (200 mg and 500 mg) (2H 2022)
- Present safety data from the Phase 1b combination trial with palbociclib (2H 2022)
- Initiate two Phase 3 trials in patients with metastatic breast cancer (as monotherapy and in combination)
- Initiate a Phase 1b combination trial with CDK inhibitors or other targeted therapies
- Initiate a Phase 1b combination trial with everolimus
- Initiate a Phase 2 neoadjuvant trial in patients with early breast cancer

Bavdegalutamide (ARV-110)

- Discuss the potential accelerated approval path with the Food and Drug Administration (FDA) (1H 2022)
- Finalize partnership for a companion diagnostic (1H 2022)
- Initiate a pivotal trial in mCRPC for patients with AR T878/H875 tumor mutations (2H 2022)

ARV-766

- Share Phase 1 dose escalation data in mCRPC (2H 2022)
- Initiate Phase 2 expansion trial in mCRPC (2H 2022)

Full Year and Fourth Quarter Financial Results
Cash, Cash Equivalents and Marketable Securities Position: As of December 31, 2021, cash, cash equivalents, restricted cash and marketable securities were $1,507.1 million, as compared with $688.6 million as of December 31, 2020. The increase in cash, cash equivalents, restricted cash and marketable securities of $818.5 million for the year was primarily related to cash received from the global Pfizer collaboration agreement to develop and commercialize ARV-471 (ARV-471 Collaboration Agreement) of $650.0 million, the equity investment by Pfizer of $350.0 million and proceeds from the exercise of stock options of $18.6 million, partially offset by cash used in operating activities of $172.7 million (net of $4.2 million received from two collaborators), professional fees associated with the ARV-471 Collaboration Agreement and equity investment of $17.5 million, the purchase of lab equipment and leasehold improvements of $4.7 million and unrealized loss on marketable securities of $5.2 million.

Research and Development Expenses: Research and development expenses were $180.4 million and $61.8 million for the year and quarter ended December 31, 2021, respectively as compared with $108.4 million and $33.2 million for the year and quarter ended December 31, 2020, respectively. The increase in research and development expenses of $72.0 million for the year ended December 31, 2021, was primarily due to an increase in expenses associated with our platform and exploratory programs of $41.2 million, our AR program (which includes bavdegalutamide and ARV-766) of $17.4 million and our ER program of $13.4 million. The increase in research and development expenses of $28.6 million for the quarter ended December 31, 2021, was primarily due to an increase in expenses associated with our platform and exploratory programs of $15.0 million, our AR program of $3.2 million and our ER program of $10.4 million.

General and Administrative Expenses: General and administrative expenses were $61.6 million and $18.9 million for the year and quarter ended December 31, 2021, respectively, as compared with $38.3 million and $12.2 million for the year and quarter ended December 31, 2020, respectively. The increase in general and administrative expenses of $23.3 million for the year ended December 31, 2021, was primarily due to an increase of personnel and facility related costs of $19.2 million and insurance, taxes and professional fees of $4.2 million. The increase in general and administrative expenses of $6.7 million for the quarter ended December 31, 2021was primarily due to an increase of personnel and facility related costs of $6.0 million and insurance, taxes and professional fees of $0.6 million.

Revenues: Revenue was $46.7 million and $26.3 million for the year and quarter ended December 31, 2021, respectively, as compared with $21.8 million and $2.2 million for the year and quarter ended December 31, 2020, respectively. Revenue is related to the ARV-471 Collaboration Agreement with Pfizer that was initiated in July 2021, the license and rights to technology fees and research and development activities related to the collaboration and license agreement with Bayer that was initiated in July 2019, the collaboration and license agreement with Pfizer that was initiated in January 2018 and the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017. The increase in revenue of $24.9 million and $24.1 million for the year and quarter ended December 31, 2021, respectively was primarily due to revenue from the ARV-471 Collaboration Agreement with Pfizer.

Net Loss: Net loss was $191.0 million and $53.0 million for the year and quarter ended December 31, 2021, respectively as compared with $119.3 million and $41.5 million for the year and quarter ended December 31, 2020, respectively. The increase in net loss for the year and quarter ended December 31, 2021, was primarily due to increased research and development expenses and increased general and administrative expenses, partially offset by increased revenue.

About bavdegalutamide (ARV-110)
Bavdegalutamide (ARV-110) 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 ARV-471
ARV-471 is an investigational orally bioavailable PROTAC® protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer.

In preclinical studies, ARV-471 demonstrated near-complete ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed superior anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a CDK4/6 inhibitor. In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of ARV-471; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits.

About ARV-766
ARV-766 is an investigational orally bioavailable PROTAC® protein degrader designed to selectively target and degrade AR. In preclinical studies, ARV-766 degraded all resistance-driving point mutations of AR, including L702H, a mutation associated with treatment with abiraterone and other AR-pathway therapies.

ARV-766 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer, and ARV-766 may also have applicability in other AR-driven diseases both in and outside oncology. ARV-766 has demonstrated activity in preclinical models 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.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential benefits of the Pfizer collaboration and the potential advantages and therapeutic benefits of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, the future development and potential marketing approval and commercialization of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, including the initiation of and timing of data from our clinical trials. 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:, each party’s performance of its obligations under the Pfizer collaboration, whether we and, as applicable, Pfizer will be able to successfully conduct and complete clinical development, 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.

Contacts

Investors:
Jeff Boyle
+1 (347) 247-5089
Jeff.Boyle@arvinas.com

Media:
Kirsten Owens
+1 (203) 584-0307
Kirsten.Owens@arvinas.com

ARVINAS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets (Unaudited)

(dollars and shares in millions)	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 108.3	$ 588.4
Restricted cash	4.5	-
Marketable securities	1,394.3	100.2
Accounts receivable	15.0	1.0
Other receivables	10.7	7.4
Prepaid expenses and other current assets	19.7	6.1
Total current assets	1,552.5	703.1
Property, equipment and leasehold improvements, net	12.7	12.3
Operating lease right of use assets	3.9	2.0
Collaboration contract asset and other assets	12.5	-
Total assets	$ 1,581.6	$ 717.4
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 31.3	$ 7.1
Accrued expenses	23.1	18.9
Deferred revenue	206.2	22.2
Current portion of operating lease liability	1.1	1.0
Total current liabilities	261.7	49.2
Deferred revenue	534.3	22.9
Long term debt	1.0	2.0
Operating lease liability	2.9	1.1
Total liabilities	799.9	75.2
Commitments and contingencies		
Stockholders' equity:		

Common stock, $0.001 par value, 53.0 and 48.5 shares issued and outstanding as of December 31, 2021 and 2020, respectively	-	-
Accumulated deficit	(682.9)	(491.9)
Additional paid-in capital	1,469.2	1,133.5
Accumulated other comprehensive (loss) income	(4.6)	0.6
Total stockholders' equity	781.7	642.2
Total liabilities and stockholders' equity	$ 1,581.6	$ 717.4

ARVINAS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
(dollars and shares in millions, except per share amounts)	**2021**	**2020**	**2021**	**2020**
Revenue	$ 26.3	$ 2.2	$ 46.7	$ 21.8
Operating expenses:				
Research and development	61.8	33.2	180.4	108.4
General and administrative	18.9	12.2	61.6	38.3
Total operating expenses	80.7	45.4	242.0	146.7
Loss from operations	(54.4)	(43.2)	(195.3)	(124.9)
Interest and other income	1.4	1.7	4.3	5.6
Net loss	$ (53.0)	$ (41.5)	$ (191.0)	$ (119.3)
Net loss per common share - basic and diluted	$ (1.00)	$ (0.99)	$ (3.82)	$ (3.02)
Weighted average common shares outstanding - basic and diluted	52.8	41.8	50.0	39.5