

# Arvinas Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 5, 2020

- First patient dosed in Phase 2 dose expansion cohort of ARV-110 trial -

- Dose escalation for Phase 1/2 clinical trials of ARV-110 and ARV-471 continues; program updates planned for December 2020 -

 Arvinas and Pfizer enter collaboration and supply agreement; initiation of Phase 1b combination of ARV-471 and Ibrance<sup>®</sup> expected in the fourth quarter of 2020 –

NEW HAVEN, Conn., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biopharmaceutical company creating a new class of drugs based on targeted protein degradation, today reported financial results for the third quarter ended September 30, 2020 and provided a corporate update.

"Beginning the Phase 2 portion of the ARV-110 clinical trial marks another significant milestone for Arvinas," said John Houston, Ph.D., President and Chief Executive Officer at Arvinas. "Together with the expected initiation of a cohort expansion of ARV-471 in combination with a CDK4/6 inhibitor before the end of the year, we're gratified by the strong momentum of our lead programs heading into 2021."

"When combined with our recent disclosure of five additional programs in our preclinical pipeline, these clinical milestones further validate our PROTAC® Discovery Engine and the opportunity to create PROTAC® degraders that meaningfully improve patient care," added Dr. Houston.

# **Business Highlights and Recent Developments**

- Dose escalation in each of the Phase 1/2 clinical trials of ARV-110 and ARV-471 continues.
- Arvinas has initiated dosing at a first dose level in a Phase 2 cohort expansion for ARV-110.
- The company announced platform updates and disclosed five additional programs from its preclinical pipeline. Arvinas' portfolio encompasses a range of validated and undruggable targets in oncology, immuno-oncology, and neuroscience. The newly disclosed programs were B-cell lymphoma 6 protein (BCL6), Kirsten rat sarcoma (KRAS) protein, c-Myc, hematopoietic progenitor kinase 1 (HPK1), and mutant huntingtin (mHTT).
- Arvinas entered into a collaboration and supply agreement with Pfizer in connection with a planned Phase 1b cohort expansion evaluating ARV-471 in combination with Pfizer's Ibrance <sup>®</sup> (palbociclib), an oral CDK4/6 inhibitor.

## **Anticipated Milestones and Expectations**

## 2020 Milestones and Expectations

- Arvinas expects to provide a program update for ARV-110, including a Phase 1 dose escalation update and an overview of the recently initiated Phase 2 dose expansion, in December 2020.
- For the ARV-471 program, Arvinas expects to provide an update from its Phase 1 dose escalation in December 2020.
- Arvinas expects to initiate a Phase 1b cohort expansion of ARV-471 in combination with Ibrance<sup>®</sup> (palbociclib) in the fourth quarter of 2020. The study will evaluate the safety and tolerability of ARV-471 in combination with palbociclib and identify the recommended combination dose of ARV-471 for use with palbociclib.

# 2021 Milestones and Expectations

- Arvinas expects to initiate the first of potentially two Phase 1b investigations of ARV-110 in combination with standard of care agents for mCRPC (e.g., abiraterone) in 2021.
- Arvinas expects to share interim data from the Phase 2 dose expansion trial of ARV-110 in 2021.
- Arvinas expects to initiate a Phase 2 dose expansion of ARV-471 in 2021.
- Arvinas expects to share data from the Phase 1b cohort expansion of ARV-471 in combination with Ibrance<sup>®</sup> (palbociclib) in the second half of 2021.
- Arvinas expects to file an investigational new drug (IND) application for ARV-766, an androgen receptor degrader, in the first half of 2021.

## **Financial Guidance**

Based on its current operating plan, Arvinas expects its cash, cash equivalents, and marketable securities will be sufficient to fund its planned operating expenses and capital expenditures into 2022.

# **Financial Highlights**

Cash, Cash Equivalents, and Marketable Securities Position: As of September 30, 2020, cash, cash equivalents, and marketable securities were

\$248.6 million as compared with \$280.9 million as of December 31, 2019. The decrease in cash, cash equivalents and marketable securities of \$32.3 million for the first nine months of 2020 was primarily related to cash used for operations of \$64.8 million and the purchase of lab equipment and leasehold improvements of \$4.6 million, partially offset by net proceeds from the issuance of common stock and exercises of stock options of \$33.1 million and \$4.0 million received from two collaborators.

Research and Development Expenses: Research and development expenses were \$30.0 million for the quarter ended September 30, 2020, as compared with \$16.6 million for the quarter ended September 30, 2019. The increase in research and development expenses of \$13.4 million for the quarter was primarily related to increases in clinical trials and chemistry, manufacturing and controls expenses associated with our AR program of \$4.2 million and our ER program of \$5.1 million, in addition to increases in expenses of \$4.1 million associated with exploratory programs and investments in platform research.

**General and Administrative Expenses:** General and administrative expenses were \$9.3 million for the quarter ended September 30, 2020, as compared with \$8.0 million for the quarter ended September 30, 2019. The increase of \$1.3 million was primarily related to an increase in personnel and facility related costs of \$2.4 million, offset by a reduction in legal costs of \$1.1 million.

Revenues: Revenue related to the license and rights to technology fees and research and development activities related to the collaboration and license agreement with Bayer (Bayer Collaboration Agreement) that was initiated in July 2019, the collaboration and license agreement with Pfizer (Pfizer Collaboration Agreement) that was initiated in January 2018, and the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017 (collectively Collaboration Revenue) was \$7.6 million for the quarter ended September 30, 2020, as compared with \$5.4 million for the quarter ended September 30, 2019. The increase in Collaboration Revenue of \$2.2 million primarily related to the revenues from the Bayer Collaboration Agreement and the Pfizer Collaboration Agreement. Total revenue of \$30.1 for the three months ended September 30, 2019 included \$24.7 million for the contribution of a license to Oerth Bio LLC (the Joint Venture).

Loss from Equity Method Investment: Loss from equity method investment for the quarter ended September 30, 2019 was \$24.7 million. This loss was generated from the Joint Venture's expensing the values associated with the contributed intellectual property from the Joint Venture partners.

**Net Loss:** Net loss was \$30.8 million for the quarter ended September 30, 2020, as compared with \$17.7 million for the quarter ended September 30, 2019. The increase in net loss for the quarter was primarily due to increased research and development expenses and increased general and administrative expenses.

#### **About ARV-110**

ARV-110 is an orally bioavailable PROTAC<sup>®</sup> protein degrader designed to selectively target and degrade the androgen receptor (AR). ARV-110 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer.

ARV-110 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 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.

## **About Arvinas**

Arvinas is a clinical-stage biopharmaceutical 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 two clinical-stage programs: ARV-110 for the treatment of men with metastatic castrate-resistant prostate cancer; and ARV-471 for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. For more information, visit <a href="https://www.arvinas.com">www.arvinas.com</a>.

## **Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the development and regulatory status of our product candidates ARV-110, ARV-471, ARV-766, and other candidates in our pipeline, the conduct of and plans for our ongoing Phase 1/2 clinical trials for ARV-110 and ARV-471, our planned Phase 1b combination trial for ARV-471, our planned IND filing for ARV-766, the plans for presentation of data from our Phase 1/1b/2 clinical trials for ARV-110 and ARV-471, the potential advantages and therapeutic potential of our product candidates and the sufficiency of cash resources. 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 will be able to successfully conduct Phase 1/2 clinical trials for ARV-110 and ARV-471 and Phase 1b combination trials for ARV-110 or ARV-471, complete our clinical trials for our other product candidates, and receive results from our clinical trials on our expected timelines, or at all, whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements on our expected timeline 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 for Arvinas**

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# **Arvinas, Inc.**Consolidated Statement of Operations (Unaudited)

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
		2020		2019		2020		2019
Revenue	\$	7,596,776	\$	30,050,227	\$	19,584,085	\$	38,083,205
Operating expenses:								
Research and development		30,012,918		16,588,050		75,155,694		46,779,047
General and administrative		9,331,925		7,957,364		26,072,404		20,038,772
Total operating expenses		39,344,843		24,545,414		101,228,098		66,817,819
Income (loss) from operations		(31,748,067)		5,504,813		(81,644,013)		(28,734,614)
Other income (expenses)								
Other income, net		144,215		405,302		841,967		840,153
Interest income		800,236		1,112,415		3,065,220		3,394,269
Interest expense		(16,250)		(22,903)		(48,750)		(69,319)
Total other income		928,201		1,494,814		3,858,437		4,165,103
Loss from equity method investment				(24,675,000)		_		(24,675,000)
Net loss	\$	(30,819,866)	\$	(17,675,373)	\$	(77,785,576)	\$	(49,244,511)
Net loss per common share, basic and diluted	\$	(0.79)	\$	(0.54)	\$	(2.01)	\$	(1.54)
Weighted average common shares outstanding, basic and diluted		39,058,294		32,740,486		38,784,569		31,876,074

# **Arvinas, Inc.**Consolidated Balance Sheet (Unaudited)

	September 30, 2020		December 31, 2019		
Assets					
Current assets:					
Cash and cash equivalents	\$	88,988,921	\$	9,211,057	
Marketable securities		159,574,963		271,661,456	
Account receivable		2,444,450		_	
Other receivables		3,511,633		6,280,828	
Prepaid expenses and other current assets		3,459,862		3,727,294	
Total current assets		257,979,829		290,880,635	
Property, equipment and leasehold improvements, net		11,712,403		8,455,411	
Operating lease right of use assets		2,226,422		2,278,623	
Other assets		28,777		26,757	
Total assets	\$	271,947,431	\$	301,641,426	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable	\$	5,088,034	\$	4,556,827	
Accrued expenses		12,143,734		7,602,904	
Deferred revenue		21,358,989		19,979,525	
Current portion of operating lease liability		939,761		673,896	
Total current liabilities		39,530,518		32,813,152	

Deferred revenue	23,945,470	38,427,882
Long term debt	2,000,000	2,000,000
Operating lease liability	1,351,476	1,714,111
Total liabilities	66,827,464	74,955,145
Commitments and Contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 40,096,001 and 38,461,353 shares issued and outstanding as of September		
30, 2020 and December 31, 2019, respectively	40,096	38,461
Accumulated deficit	(450,342,422)	(372,556,846)
Additional paid-in capital	654,342,486	599,097,090
Accumulated other comprehensive income	1,079,807	107,576
Total stockholders' equity	205,119,967	226,686,281
Total liabilities and stockholders' equity	\$ 271,947,431	\$ 301,641,426