



**ARCA BIOPHARMA ANNOUNCES THIRD QUARTER 2016 FINANCIAL RESULTS
AND PROVIDES BUSINESS UPDATE**

**125th Patient Randomized into the GENETIC-AF Phase 2B/3 Clinical Trial Evaluating
Gencaro as Potentially First Genetically-Targeted Treatment for Atrial Fibrillation**

**Outcome of GENETIC-AF Phase 2B Interim Efficacy Analysis Anticipated
in the Third Quarter of 2017**

Westminster, CO, November 14, 2016 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today reported financial results for the quarter ended September 30, 2016, and provided a business update.

“Atrial fibrillation is considered an epidemic cardiovascular disease impacting an estimated 33 million patients globally,” commented Dr. Michael Bristow, ARCA’s President and CEO. “Our on-going GENETIC-AF Phase 2B/3 clinical trial is evaluating Gencaro™ as potentially the first genetically-targeted treatment for atrial fibrillation. With the recent enrollment of the 125th patient in the trial, we are approaching two important milestones – the enrollment of the 150th patient, anticipated in the first quarter of 2017, and the outcome of the GENETIC-AF Data and Safety Monitoring Board Phase 2B interim efficacy analysis, projected in the third quarter of 2017. We believe there is an unmet medical need for new AF treatments that have fewer side effects than currently available therapies and are more effective, particularly in heart failure with reduced ejection fraction patients.”

GENETIC-AF Clinical Trial

GENETIC-AF is a Phase 2B/Phase 3, multi-center, randomized, double-blind, adaptive design clinical trial comparing the safety and efficacy of Gencaro to Toprol-XL (metoprolol succinate) for the treatment of atrial fibrillation (AF) in approximately 620 patients. Eligible patients will have heart failure with reduced left ventricular ejection fraction (HFREF), a history of paroxysmal AF (episodes lasting 7 days or less) or persistent AF (episodes lasting more than 7 days and less than 1 year) in the past 6 months, and the beta-1 389 arginine homozygous genotype that the Company believes responds most favorably to Gencaro. The primary endpoint of the study is time to first event of symptomatic AF/atrial flutter (AFL) or all-cause mortality. The combined Phase 2B/Phase 3 trial is designed for 90 percent power at a p-value of less than 0.01 significance level to detect a 25 percent reduction in the primary endpoint for patients in the Gencaro arm compared to patients in the Toprol-XL arm. The trial is currently enrolling patients in the United States, Canada and certain European countries. To date, 125 patients have been randomized into the trial.

The GENETIC-AF Data and Safety Monitoring Board (DSMB) will conduct a pre-specified interim analysis of study endpoints for efficacy, safety and futility to recommend whether or not the trial should proceed to Phase 3. The DSMB will make its recommendation based on a predictive probability analysis of certain trial data after at least 150 patients have evaluable endpoint data. An enrolled patient has evaluable endpoint data either when they experience their first endpoint event, or after they complete the 24-week follow up period. The DSMB interim analysis will focus on analyses of the AF/AFL endpoints in the trial using both clinical-based intermittent monitoring and device-based continuous monitoring techniques. Based on the results of the interim analysis, the DSMB may recommend that the trial proceed to Phase 3, the trial be completed as a Phase 2B study, or termination of the trial due to futility. ARCA, in collaboration with the GENETIC-AF Steering Committee, will determine the next steps for the trial based on the DSMB recommendation from this interim analysis and on the Company's available financing. Based on ARCA's current enrollment projections, the Company now expects to reach 150 patients enrolled in the trial during the first quarter of 2017. The Company projects that the outcome of the DSMB interim analysis and recommendation will be available in the third quarter of 2017.

Third Quarter 2016 Summary Financial Results

Cash, cash equivalents and marketable securities totaled \$27.4 million as of September 30, 2016, compared to \$38.8 million as of December 31, 2015. The Company believes that its current cash, cash equivalents and marketable securities will be sufficient to fund its operations, at its projected cost structure, through at least the end of 2017. ARCA had approximately 9.1 million outstanding shares of common stock as of September 30, 2016.

Research and development (R&D) expense for the three months ended September 30, 2016 was \$3.7 million compared to \$1.7 million for the corresponding period of 2015, an increase of approximately \$2.0 million. R&D expense for the nine months ended September 30, 2016 was \$9.2 million compared to \$5.2 million for the corresponding period of 2015, an increase of approximately \$4.1 million. The increase in R&D expense in the three and nine month periods ended September 30, 2016 is due, primarily, to the increased clinical expense of the GENETIC-AF clinical trial. The Company expects R&D expense in 2016 to be higher than 2015 as it activates new clinical sites and enrolls additional patients in the GENETIC-AF clinical trial.

General and administrative (G&A) expense for the three months ended September 30, 2016 was \$1.0 million compared to \$1.1 million for the corresponding period in 2015. G&A expense was \$3.1 million for the nine months ended September 30, 2016 as compared to \$3.1 million for the corresponding period in 2015. The Company expects G&A expense in 2016 will be higher than in 2015 as the Company increases administrative activities to support the GENETIC-AF clinical trial.

Total operating expense for the three months ended September 30, 2016 was \$4.7 million compared to \$2.8 million for the corresponding period in 2015. Total operating expense for the nine months ended September 30, 2016 was \$12.3 million compared to \$8.3 million for the corresponding period in 2015.

Net loss was \$4.7 million, or \$0.51 per share, for the third quarter of 2016, compared to \$2.8 million, or \$0.31 per share, for the third quarter of 2015. For the first nine months of 2016, net loss was \$12.2 million, or \$1.35 per share, compared to \$8.3 million, or \$1.54 per share, for the first nine months of 2015.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation. ARCA has identified common genetic variations that it believes predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted atrial fibrillation prevention treatment. ARCA has a collaboration with Medtronic, Inc. for support of the GENETIC-AF trial. For more information, please visit www.arcabio.com.

Safe Harbor Statement

This press release contains "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding, potential timing for patient enrollment in the GENETIC-AF trial, potential timeline for GENETIC-AF trial activities and related recommendations of the DSMB, the sufficiency of the Company's capital to support its operations, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, future treatment options for patients with atrial fibrillation, and the potential for Gencaro to be the first genetically-targeted atrial fibrillation prevention treatment. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; results of earlier clinical trials may not be confirmed in future trials, the protection and market exclusivity provided by the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; and, the impact of competitive products and technological changes. These and other factors are identified and described in more detail in ARCA's filings with the SEC, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2015, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

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(Tables Follow)

ARCA BIOPHARMA, INC.
BALANCE SHEET DATA
(in thousands)
(unaudited)

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
Cash, cash equivalents and marketable securities	\$27,435	\$38,802
Working capital	\$21,632	\$37,412
Total assets	\$28,679	\$39,574
Total stockholders' equity	\$26,480	\$38,070

ARCA BIOPHARMA, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
	(in thousands, except share and per share amounts)			
Costs and expenses:				
Research and development	\$ 3,720	\$ 1,716	\$ 9,227	\$ 5,170
General and administrative	992	1,101	3,094	3,110
Total costs and expenses	4,712	2,817	12,321	8,280
Loss from operations	(4,712)	(2,817)	(12,321)	(8,280)
Interest and other income	53	4	121	7
Interest expense	—	(1)	—	(4)
Net loss	<u>\$ (4,659)</u>	<u>\$ (2,814)</u>	<u>\$ (12,200)</u>	<u>\$ (8,277)</u>
Change in unrealized loss on marketable securities	(19)	—	(6)	—
Comprehensive loss	<u>\$ (4,678)</u>	<u>\$ (2,814)</u>	<u>\$ (12,206)</u>	<u>\$ (8,277)</u>
Net loss per share:				
Basic and diluted	\$ (0.51)	\$ (0.31)	\$ (1.35)	\$ (1.54)
Weighted average shares outstanding:				
Basic and diluted	9,068,376	9,034,016	9,062,516	5,358,629