



## ARCA BIOPHARMA ANNOUNCES THIRD QUARTER 2017 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

### ----- GENETIC-AF Phase 2B Clinical Trial Data Anticipated in First Quarter of 2018

Westminster, CO, November 9, 2017 – [ARCA biopharma, Inc.](#) (Nasdaq: ABIO), a biopharmaceutical company applying a [precision medicine](#) approach to developing genetically-targeted therapies for cardiovascular diseases, today reported financial results for the quarter ended September 30, 2017, and provided a business update.

“With enrollment completed in the [GENETIC-AF](#) clinical trial evaluating Gencaro as potentially the first genetically-targeted treatment for atrial fibrillation, we are finishing patient follow-up and anticipate reporting top-line data late in the first quarter of 2018,” commented [Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer. “We are focused on executing our genetically-targeted approach to cardiovascular drug development and look forward to furthering our development of Gencaro as well as initiating additional pharmacogenetic development programs.”

### Third Quarter 2017 Summary Financial Results

**Cash, cash equivalents and marketable securities** totaled \$16.0 million as of September 30, 2017, compared to \$23.5 million as of December 31, 2016. ARCA had approximately 11.75 million outstanding shares of common stock as of September 30, 2017. ARCA believes that its current cash, cash equivalents and marketable securities will be sufficient to fund its operations, at its projected cost structure, through the end of second quarter of 2018.

**Research and development (R&D) expenses** for the three months ended September 30, 2017 totaled \$3.5 million compared to \$3.7 million for the corresponding period of 2016, a decrease of approximately \$0.2 million. R&D expense for the nine months ended September 30, 2017 totaled \$11.2 million compared to \$9.2 million for the corresponding period of 2016, an increase of approximately \$2.0 million. The changes in R&D expenses in the three and nine month periods ended September 30, 2017 was due primarily to the increased expense of ARCA’s GENETIC-AF clinical trial. The Company expects R&D expenses in 2017 to be higher than 2016 as it reached peak patient screening activity and patient enrollment for the GENETIC-AF clinical trial during 2017.

**General and administrative (G&A) expenses** for the three months ended September 30, 2017 were \$1.0 million compared to \$1.0 million for the corresponding period in 2016. G&A expenses totaled \$3.2 million for the nine months ended September 30, 2017 as compared to \$3.1 million for the corresponding period in 2016, a net increase of approximately \$79,000. The increase for

the nine periods was comprised primarily of higher consulting costs and professional fees, partially offset by decreased non-cash, stock-based compensation expense in 2017, as compared to the corresponding period in 2016. ARCA expects G&A expenses in 2017 to be higher than in 2016 due to increased administrative activities to support the GENETIC-AF clinical trial and costs incurred in the fourth quarter of 2017 for the acquisition of certain Gencaro license rights from Aeolus Pharmaceuticals, Inc. which previously held certain royalty rights on the Gencaro program.

**Total operating expenses** for the three months ended September 30, 2017 were \$4.5 million compared to \$4.7 million for the corresponding period in 2016. Total operating expenses for the nine months ended September 30, 2017 were \$14.4 million compared to \$12.3 million for the corresponding period in 2016. The changes in total operating for the nine month periods was primarily due to the increase in R&D expense due to the increased clinical expense of the GENETIC-AF clinical trial.

**Net loss** was \$4.4 million, or \$0.39 per share, for the third quarter of 2017 compared to \$4.7 million, or \$0.51 per share, for the third quarter of 2016. Net loss for the nine months ended September 30, 2017 was \$14.3 million, or \$1.43 per share, compared to \$12.2 million, or \$1.35 per share, for the corresponding period in 2016.

### **GENETIC-AF Clinical Trial**

GENETIC-AF is a Phase 2B, multi-center, randomized, double-blind, superiority clinical trial comparing the safety and efficacy of Gencaro to Toprol-XL (metoprolol succinate) for the treatment and prevention of recurrent atrial fibrillation or flutter (AF/AFL) in heart failure patients with reduced left ventricular ejection fraction (HFrEF). Eligible patients have 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 ARCA believes responds most favorably to Gencaro. The GENETIC-AF Data and Safety Monitoring Board (DSMB) conducted a pre-specified interim analysis of all patients randomized as of June 19, 2017. Based on its efficacy and safety review, the DSMB recommended completion of the Phase 2B trial with no changes to the trial design and indicated that there were no safety concerns.

### **About ARCA biopharma**

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. ARCA's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for the potential treatment of patients with atrial fibrillation and HFrEF, currently in a Phase 2B clinical trial. 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. The Gencaro development program has been granted Fast Track designation by the FDA. For more information, please visit [www.arcabio.com](http://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, the potential timeline for GENETIC-AF trial activities, potential timing for the announcement of topline data for the Phase 2B GENETIC-AF trial, the sufficiency of ARCA's capital to support its operations, the expected features and characteristics of Gencaro, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, future treatment options for patients with AF, and the potential for Gencaro to be the first genetically-targeted AF 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: ARCA's financial resources and whether they will be sufficient to meet its business objectives and operational requirements; results of earlier clinical trials may not be confirmed in future trials; the protection and market exclusivity provided by ARCA'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 Securities and Exchange Commission, including without limitation ARCA's annual report on Form 10-K for the year ended December 31, 2016, and subsequent filings. ARCA 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, 2017</u>	<u>December 31, 2016</u>
Cash, cash equivalents & marketable securities	\$15,951	\$23,515
Working capital	\$13,832	\$19,049
Total assets	\$16,921	\$24,629
Total stockholders' equity	\$14,352	\$22,194

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(in thousands, except share and per share amounts)			
<b>Costs and expenses:</b>				
Research and development	\$ 3,488	\$ 3,720	\$ 11,242	\$ 9,227
General and administrative	987	992	3,173	3,094
Total costs and expenses	4,475	4,712	14,415	12,321
Loss from operations	(4,475)	(4,712)	(14,415)	(12,321)
Interest and other income	44	53	128	121
Interest expense	(2)	—	(6)	—
Net loss	<u>\$ (4,433)</u>	<u>\$ (4,659)</u>	<u>\$ (14,293)</u>	<u>\$ (12,200)</u>
Change in unrealized loss on marketable securities	2	(19)	16	(6)
Comprehensive loss	<u>\$ (4,431)</u>	<u>\$ (4,678)</u>	<u>\$ (14,277)</u>	<u>\$ (12,206)</u>
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.39)	\$ (0.51)	\$ (1.43)	\$ (1.35)
<b>Weighted average shares outstanding:</b>				
Basic and diluted	11,502,654	9,068,376	9,982,739	9,062,516