



## ARCA BIOPHARMA ANNOUNCES FIRST QUARTER 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

### ----- End-of-Phase 2 Meeting with the U.S. FDA Scheduled for the Last Week of June to Review Gencaro Phase 2 Data and Future Development Plan

Westminster, CO, May 8, 2018 – 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 March 31, 2018.

“The first quarter of this year saw an important milestone for the Gencaro development program with the reporting of top-line Phase 2B results for the GENETIC-AF clinical trial evaluating Gencaro as potentially the first genetically-targeted treatment for atrial fibrillation,” commented Dr. Michael Bristow, ARCA’s President and Chief Executive Officer. “Our End-of-Phase 2 meeting with the U.S. FDA is scheduled for the last week of June when we will review the data and potential future development plans for Gencaro.”

### Pipeline Update

**Gencaro** (bucindolol hydrochloride) - a pharmacologically unique beta-blocker and mild vasodilator being developed for the potential treatment of patients with atrial fibrillation (AF) and chronic heart failure with reduced left ventricular ejection fraction (HFrEF).

- ARCA reported (February 26, 2018) top-line data for GENETIC-AF Phase 2B clinical trial evaluating Gencaro as potential treatment for atrial fibrillation.
  - In all patients, Gencaro demonstrated a similar treatment benefit compared to the active control, metoprolol succinate (TOPROL-XL) (143 total events, hazard ratio of 1.01 (95% confidence interval: 0.71, 1.42). In U.S. patients (127 of 267 total patients), a trend for potential benefit in favor of Gencaro (approximately 30% risk reduction over TOPROL-XL), was observed for the primary endpoint of time to recurrence of AF (73 events, hazard ratio 0.70, [0.41, 1.19]). Safety data indicated that Gencaro was generally safe and well-tolerated in the AF/heart failure (HF) population investigated with a safety profile similar to TOPROL-XL.
  - Further analysis of the GENETIC-AF trial data indicates the regional heterogeneity observed may be attributable to differences in baseline characteristics of enrolled patients, specifically differences in the underlying pathophysiology leading to the development of AF.

- An End-of-Phase 2 meeting is scheduled with the U.S. Food and Drug Administration (FDA) for the last week of June to review the GENETIC-AF data and potential future Gencaro development plans. Within 30 days following the meeting, the FDA will provide written minutes of the meeting to confirm the discussions. ARCA plans to provide an update on Gencaro potential future development plans subsequent to receiving the FDA meeting minutes.
- In April 2018, Medtronic, Inc. and ARCA agreed to extend their current U.S., Canadian and European Clinical Trial Collaboration Agreement for one additional year.

**AB171** – a thiol-substituted isosorbide mononitrate being developed as a potential genetically-targeted treatment for peripheral arterial disease (PAD) and for heart failure (HF).

- Chemistry, manufacturing and controls (CMC) activities initiated in first quarter of 2018.

### **First Quarter 2018 Summary Financial Results**

**Cash, cash equivalents and marketable securities** totaled \$12.1 million as of March 31, 2018, compared to \$11.8 million as of December 31, 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 2018.

**Research and development (R&D) expenses** for the quarter ended March 31, 2018 totaled \$1.7 million compared to \$3.2 million for the corresponding period of 2017. The \$1.5 million decrease in research and development expenses in the first quarter of 2018 as compared to the first quarter 2017 was primarily due to decreased clinical expenses following the completion of the GENETIC-AF clinical trial. The Company expects R&D expenses in 2018 to be lower than 2017 as the GENETIC-AF clinical trial has been completed.

**General and administrative (G&A) expenses** for the quarter ended March 31, 2018 were \$1.1 million, similar to the \$1.1 million in the first quarter of 2017. ARCA expects G&A expenses in 2018 to be consistent with those in 2017 as it maintains administrative activities to support ongoing operations.

**Total operating expenses** for the quarter ended March 31, 2018 were \$2.8 million compared to \$4.4 million for the first quarter of 2017. The decrease in total operating expenses for the first quarter of 2018 was primarily due to the decrease in R&D expense due to the completion of the GENETIC-AF clinical trial.

**Net loss** was \$2.7 million, or \$0.20 per share, for the first quarter of 2018 compared to \$4.3 million, or \$0.48 per share, for the first quarter of 2017.

## 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 (AF) and chronic heart failure with reduced left ventricular ejection fraction (HFrEF) which recently completed 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 AF 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 FDA. ARCA also plans to develop AB171, a thiol-substituted isosorbide mononitrate, as a potential genetically-targeted treatment for peripheral arterial disease (PAD) and for heart failure (HF). 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 ability of ARCA's financial resources to support its operations through the end of 2018, potential future development plans for Gencaro, the expected features and characteristics of Gencaro or AB171, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, AB171's potential to treat HF, 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; ARCA may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations in the future; 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, 2017, 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>March 31, 2018</u>	<u>December 31, 2017</u>
Cash, cash equivalents & marketable securities	\$12,096	\$11,752
Working capital	\$11,008	\$10,229
Total assets	\$12,788	\$12,365
Total stockholders' equity	\$11,054	\$10,275

**ARCA BIOPHARMA, INC.**

**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(in thousands, except share and per share amounts)</b>	
<b>Costs and expenses:</b>		
Research and development	\$ 1,720	\$ 3,246
General and administrative	1,053	1,135
Total costs and expenses	2,773	4,381
Loss from operations	(2,773)	(4,381)
Interest and other income	41	45
Interest expense	(3)	(2)
Net loss	<u>\$ (2,735)</u>	<u>\$ (4,338)</u>
Change in unrealized loss on marketable securities	2	10
Comprehensive loss	<u>\$ (2,733)</u>	<u>\$ (4,328)</u>
<b>Net loss per share:</b>		
Basic and diluted	\$ (0.20)	\$ (0.48)
<b>Weighted average shares outstanding:</b>		
Basic and diluted	13,620,710	9,094,276