



ARCA BIOPHARMA ANNOUNCES THIRD QUARTER 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Westminster, CO, November 14, 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 September 30, 2018 and provided a corporate update.

“We remain focused on advancing the development of our pipeline of genetically-targeted therapeutics to address the unmet medical needs of patients with cardiovascular disease,” commented Dr. Michael Bristow, ARCA’s President and Chief Executive Officer. “FDA is currently giving further consideration to our SPA application for the Phase 3 clinical trial of Gencaro following our provision of supporting information in response to an initial No Agreement letter. We have requested a meeting with the FDA and look forward to meeting with them in December to discuss any remaining issues in the application.”

Pipeline Update

GencaroTM (bucindolol hydrochloride) - a pharmacologically unique beta-blocker and mild vasodilator being developed as a potential genetically-targeted treatment for heart failure (HF) patients at risk for atrial fibrillation (AF).

- At the end of October, the Company received a *No Agreement* letter from the U.S. Food and Drug Administration (FDA) on its Special Protocol Assessment (SPA) application for the Phase 3 PRECISION-AF clinical trial. After further correspondence with the FDA and the provision of information supporting the SPA application, the FDA has agreed to reconsider the SPA request. ARCA has requested a meeting with the FDA to review the SPA application, which the Company anticipates will occur in December.

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

- Chemistry, manufacturing and controls (CMC) activities were continued in the third quarter.
- IND-enabling non-clinical studies are anticipated to begin in the first half of 2019.

Third Quarter 2018 Summary Financial Results

Cash, cash equivalents and marketable securities totaled \$8.1 million as of September 30, 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 the first quarter of 2019.

Research and development (R&D) expenses for the quarter ended September 30, 2018 totaled \$0.7 million compared to \$3.5 million for the corresponding period of 2017. The \$2.7 million decrease in R&D expenses in the third quarter of 2018 as compared to the third 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 September 30, 2018 were \$0.9 million, relatively unchanged compared to the \$1.0 million in the third 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 September 30, 2018 were \$1.7 million compared to \$4.5 million for the third quarter of 2017. The decrease in total operating expenses for the second 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 \$1.6 million, or \$0.11 per share, for the third quarter of 2018 compared to \$4.4 million, or \$0.39 per share, for the third 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 heart failure (HF) patients at risk for atrial fibrillation (AF). 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. The Gencaro development program has been granted Fast Track designation by FDA. ARCA is also developing 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.

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 the first quarter of 2019, 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)

September 30, 2018 December 31, 2017

Cash, cash equivalents & marketable securities	\$8,056	\$11,752
Working capital	\$7,414	\$10,229
Total assets	\$8,445	\$12,365
Total stockholders' equity	\$7,463	\$10,275

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

Three Months Ended

Nine Months Ended

September 30,

September 30,

2018

2017

2018

2017

(in thousands, except share and per share amounts)

Costs and expenses:

Research and development	\$ 740	\$ 3,488	\$ 3,614	\$ 11,242
General and administrative	922	987	2,977	3,173
Total costs and expenses	1,662	4,475	6,591	14,415
Loss from operations	<u>(1,662)</u>	<u>(4,475)</u>	<u>(6,591)</u>	<u>(14,415)</u>
Interest and other income	40	44	124	128
Interest expense	<u>(2)</u>	<u>(2)</u>	<u>(8)</u>	<u>(6)</u>
Loss before income taxes	(1,624)	(4,433)	(6,475)	(14,293)
Benefit from income taxes	31	—	31	—
Net loss	<u>\$ (1,593)</u>	<u>\$ (4,433)</u>	<u>\$ (6,444)</u>	<u>\$ (14,293)</u>

Change in unrealized loss on marketable securities

	<u>—</u>	<u>2</u>	<u>2</u>	<u>16</u>
Comprehensive loss	<u>\$ (1,593)</u>	<u>\$ (4,431)</u>	<u>\$ (6,442)</u>	<u>\$ (14,277)</u>

Net loss per share:

Basic and diluted	\$ (0.11)	\$ (0.39)	\$ (0.47)	\$ (1.43)
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Weighted average shares outstanding:

Basic and diluted	13,923,825	11,502,654	13,823,793	9,982,739
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