



ARCA BIOPHARMA ANNOUNCES THIRD QUARTER 2019 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- *PRECISION-AF pivotal Phase 3 clinical trial initiation anticipated first quarter of 2020*
- *Trial to examine atrial fibrillation in a heart failure population for which there are no FDA indicated drug therapies*

Westminster, CO, November 6, 2019 – [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, 2019 and provided a corporate update.

“There are currently no FDA approved drug therapies indicated for treating patients with atrial fibrillation and heart failure with left ventricular ejection fraction values greater than 40%,” commented [Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer. “Approximately two-thirds of all heart failure patients have LVEF values greater than 40% and about half of these patients will develop atrial fibrillation. Based on our Phase 2 data, we believe Gencaro has the potential to help address this substantial unmet medical need. We look forward to further evaluating Gencaro in the planned Phase 3 clinical trial, PRECISION-AF, which we plan to initiate in the first quarter of 2020.”

Pipeline Update

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

- In July 2019, the U.S. Food and Drug Administration (FDA) agreed to amend ARCA’s Special Protocol Assessment (SPA) agreement for the Phase 3 PRECISION-AF clinical trial to expand the target trial population to include heart failure patients with left ventricular ejection fractions (LVEF) $\geq 40\%$ and $\leq 55\%$. Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF in the first quarter of 2020.
- In September 2019, Gencaro AF clinical data from the GENETIC-AF Phase 2B trial was presented at the Heart Failure Society of America (HFSA) 2019 Annual Scientific Meeting. The data indicate Gencaro response appears to be greater in HF patients with less severe left ventricular dysfunction, a patient population with no FDA approved drug therapeutic options for AF prevention or heart failure.

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

- Chemistry, manufacturing and controls (CMC) activities continued in the third quarter.
- Subject to securing additional financing, Investigational New Drug (IND)-enabling non-clinical studies are anticipated to begin in the first quarter of 2020, and an IND submission is anticipated in the second half of 2020.

Third Quarter 2019 Summary Financial Results

Cash and cash equivalents were \$9.6 million as of September 30, 2019, compared to \$6.6 million as of December 31, 2018. ARCA believes that its current cash and cash equivalents will be sufficient to fund its operations, at its current cost structure, after giving effect to potential cost reductions, through the third quarter of 2020.

Research and development (R&D) expenses for the three months ended September 30, 2019 were \$0.3 million compared to \$0.7 million for the corresponding period of 2018. The decrease in R&D expenses was primarily due to decreased clinical expenses following the completion of the GENETIC-AF clinical trial in 2018. The Company does not anticipate having any material clinical trial expense in 2019, consequently R&D expense in 2019 is expected to be lower than in 2018.

General and administrative (G&A) expenses were relatively unchanged at \$0.9 million for both the three months ended September 30, 2019 and 2018. The Company expects G&A expenses in 2019 to be consistent with those in 2018 as it maintains administrative activities to support its ongoing operations.

Total operating expenses for the three months ended September 30, 2019 were \$1.2 million compared to \$1.7 million for the corresponding period of 2018. The decrease in total operating expenses was primarily attributable to the decrease in R&D expense due to the completion of the GENETIC-AF clinical trial in 2018.

Net loss was \$1.2 million, or \$0.76 per share, for the third quarter of 2019 compared to \$1.6 million, or \$2.06 per share, for the third quarter of 2018.

The Company will need to raise additional capital, and/or complete a partnership or other possible strategic transaction, to fund future operations and develop Gencaro or any other product candidates.

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 atrial fibrillation in heart failure patients. 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 heart failure and peripheral arterial disease. For more information, please visit www.arcabio.com or follow the Company on [LinkedIn](#).

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 third quarter of 2020, 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 or PAD, 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, 2018, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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(Tables follow)

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ARCA BIOPHARMA, INC.

BALANCE SHEET DATA

(in thousands)

(unaudited)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Cash and cash equivalents	\$9,645	\$6,608
Working capital	\$8,754	\$5,984
Total assets	\$9,949	\$6,825
Total stockholders' equity	\$8,799	\$6,032

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018

(in thousands, except share and per share amounts)

Costs and expenses:				
Research and development	\$ 347	\$ 740	\$ 1,449	\$ 3,614
General and administrative	900	922	3,087	2,977
Total costs and expenses	1,247	1,662	4,536	6,591
Loss from operations	(1,247)	(1,662)	(4,536)	(6,591)
Interest and other income	50	40	136	124
Interest expense	(1)	(2)	(7)	(8)
Loss before income taxes	(1,198)	(1,624)	(4,407)	(6,475)
Income tax benefit	42	31	151	31
Net loss	<u>\$ (1,156)</u>	<u>\$ (1,593)</u>	<u>\$ (4,256)</u>	<u>\$ (6,444)</u>
Change in unrealized loss on marketable securities	—	—	—	2
Comprehensive loss	<u>\$ (1,156)</u>	<u>\$ (1,593)</u>	<u>\$ (4,256)</u>	<u>\$ (6,442)</u>
Net loss per share:				
Basic and diluted	\$ (0.76)	\$ (2.06)	\$ (3.46)	\$ (8.39)
Weighted average shares outstanding:				
Basic and diluted	1,521,259	773,545	1,229,289	767,989