ARCA BIOPHARMA ANNOUNCES FISCAL YEAR 2019 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- ***U.S. FDA Special Protocol Assessment agreement for a single pivotal Phase 3 clinical trial (PRECISION-AF) of genetically-targeted Gencaro***
- ***PRECISION-AF clinical trial initiation anticipated fourth quarter of 2020***
- ***Trial to evaluate Gencaro as a potential treatment for prevention of atrial fibrillation in a heart failure population for which there are no FDA indicated drug therapies***

Westminster, CO, February 18, 2020 – 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 year ended December 31, 2019 and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "During 2019, we continued to advance development of Gencaro as a potential genetically-targeted treatment for heart failure patients with atrial fibrillation. In published or submitted for presentation/publication material, we have identified important new effectiveness evidence from the GENETIC-AF trial that have enhanced our understanding of the clinical profile of Gencaro. These data have allowed us to broaden the design of the single, pivotal Phase 3 clinical trial that was developed after consultation with the U.S. Food and Drug Administration via a Special Protocol Assessment agreement. There are currently no FDA approved drug therapies indicated for the treatment of atrial fibrillation in heart failure patients with left ventricular ejection fraction values greater than 40%. Based on our clinical data to date, we believe Gencaro has the potential to help address this substantial unmet medical need. We look forward to further evaluating the pharmacogenetic benefits of Gencaro for patients with our targeted genetic profile in PRECISION-AF, the Phase 3 clinical trial, which, subject to obtaining additional financing, we plan to initiate in the fourth quarter of 2020."

Pipeline Update – Second Half Review

Gencaro™ (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).

- The U.S. Food and Drug Administration (FDA) issued a Special Protocol Assessment (SPA) agreement for a single Phase 3 clinical trial (PRECISION-AF) to examine Gencaro as a genetically-targeted therapy for the prevention of AF recurrence in certain heart failure patients.

- PRECISION-AF is designed as a double-blind, active-controlled, multicenter, international, adaptive study comparing Gencaro with TOPROL-XL (metoprolol succinate) for the prevention of AF recurrence or all-cause mortality in approximately 400 heart failure patients who have left ventricular injection fraction (LVEF) values ≥ 40% and ≤ 55% and the genotype which ARCA believes responds best to Gencaro (ADRB1 Arg389Arg).

- Clinical data from the GENETIC-AF Phase 2B clinical trial was published in the Journal of the American College of Cardiology: Heart Failure in May 2019 and was presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting in September 2019. These data indicate that the response to Gencaro may 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.

- Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF in the fourth quarter of 2020.

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

- Subject to securing additional financing, the Company anticipates conducting non-clinical studies to support a potential IND submission and initiation of clinical development in 2021.

2019 Summary Financial Results

Cash and cash equivalents were $8.4 million as of December 31, 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 end of the third quarter of 2020.

Research and development (R&D) expenses for the year ended December 31, 2019 were $1.8 million compared to $4.2 million for 2018. The $2.4 million decrease was primarily due to decreased clinical expenses following the completion of the GENETIC-AF clinical trial. If the PRECISION-AF clinical trial is initiated in the second half of 2020, R&D expense in 2020 is expected to be higher than 2019.

General and administrative (G&A) expenses were $4.0 million for 2019 compared to $3.9 million for 2018. The Company expects G&A expenses in 2020 to be consistent with those in 2019 as it maintains administrative activities to support its ongoing operations.

Total operating expenses for 2019 were $5.8 million compared to $8.1 million for 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.

Net loss was $5.5 million, or $4.15 per basic and diluted share, for 2019 compared to $7.9 million, or $10.31 per basic and diluted share, for 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 U.S. FDA has granted the Gencaro development program Fast Track designation and a Special Protocol Assessment (SPA) agreement for a single Phase 3 clinical trial. 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, 2019, 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)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$8,363	$6,608
Working capital	$7,554	$5,984
Total assets	$8,536	$6,825
Total stockholders' equity	$7,610	$6,032

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Years Ended December 31,	
	2019	**2018**
	(in thousands, except share and per share amounts)	
Costs and expenses:		
Research and development	$ 1,833	$ 4,239
General and administrative	3,981	3,879
Total costs and expenses	5,814	8,118
Loss from operations	(5,814)	(8,118)
Interest and other income	172	162
Interest expense	(7)	(8)
Loss before income taxes	(5,649)	(7,964)
Income tax benefit	167	31
Net loss	$ (5,482)	$ (7,933)
Change in unrealized loss on marketable securities	—	2
Comprehensive loss	$ (5,482)	$ (7,931)
Net loss per share:		
Basic and diluted	$ (4.15)	$ (10.31)
Weighted average shares outstanding:		
Basic and diluted	1,321,234	769,392