



ARCA BIOPHARMA ANNOUNCES FIRST QUARTER 2020 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- *U.S. FDA Special Protocol Assessment agreement for PRECISION-AF, a single pivotal Phase 3 clinical trial of genetically targeted Gencaro*
- *PRECISION-AF 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*
- *PRECISION-AF clinical trial initiation anticipated fourth quarter*

Westminster, CO, May 6, 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 first quarter of 2020 and provided a corporate update.

[Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer, commented, “During this time of national and global health crisis, ARCA has acted to address uncertainty with a focus on three key areas: protecting the health and well-being of our employees, continuing effective operations to support advancing the development of Gencaro as a potential genetically targeted treatment for heart failure patients with atrial fibrillation, and seeking additional funding, whether through direct financing or on-going partnering discussions. Our planned Phase 3 clinical trial addresses a patient population for which there are currently no FDA approved drug therapies and we believe Gencaro has the potential to help address this substantial unmet medical need.”

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).

- 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 $\geq 40\%$ and $\leq 55\%$ and the genotype which ARCA believes responds best to Gencaro (ADRB1 Arg389Arg).

- 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.

First Quarter 2020 Summary Financial Results

Cash and cash equivalents were \$6.7 million as of March 31, 2020, compared to \$8.4 million as of December 31, 2019. 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 three months ended March 31, 2020 were \$0.4 million compared to \$0.7 million for the corresponding period in 2019, a decrease of approximately \$0.3 million. The decrease was primarily due to decreased R&D personnel costs and lower outside services and consulting costs.

General and administrative (G&A) expenses were \$1.0 million for the three months ended March 31, 2020 compared to \$1.1 million for the corresponding period in 2019. 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 the three months ended March 31, 2020 were \$1.3 million compared to \$1.8 million for the corresponding period in 2019.

Net loss for the three months ended March 31, 2020 was \$1.3 million, or \$0.83 per basic and diluted share, compared to \$1.7 million, or \$1.86 per basic and diluted share, for the corresponding period in 2019.

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)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$6,674	\$8,363
Working capital	\$6,223	\$7,554
Total assets	\$7,461	\$8,536
Total stockholders' equity	\$6,306	\$7,610

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended	
	March 31,	
	2020	2019
	(in thousands, except share and per share amounts)	
Costs and expenses:		
Research and development	\$ 365	\$ 662
General and administrative	975	1,119
Total costs and expenses	1,340	1,781
Loss from operations	(1,340)	(1,781)
Interest and other income	24	38
Interest expense	(4)	(3)
Loss before income taxes	(1,320)	(1,746)
Income tax benefit	—	82
Net loss	<u>\$ (1,320)</u>	<u>\$ (1,664)</u>
Net loss per share:		
Basic and diluted	\$ (0.83)	\$ (1.86)
Weighted average shares outstanding:		
Basic and diluted	1,594,070	895,970