



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

- *FDA SPA Agreement for Phase 3 atrial fibrillation trial (PRECISION-AF) amended to expand patient population to include heart failure patients with preserved ejection fraction (HFpEF)*
- *PRECISION-AF clinical trial initiation anticipated in the first quarter of 2020*

Westminster, CO, August 1, 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 June 30, 2019 and provided a corporate update.

“We continue to make important progress on our lead development program Gencaro building on our GENETIC-AF Phase 2B clinical trial results, which were published in the Journal of the American College of Cardiology: Heart Failure,” commented [Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer. “The U.S. FDA recently agreed to amend the Special Protocol Assessment agreement for our Phase 3 trial to include heart failure patients with preserved ejection fraction (HFpEF) and a left ventricular ejection fraction (LVEF) up to 55%, the upper boundary of the LVEF range in GENETIC-AF for which Gencaro exhibited effectiveness for preventing atrial fibrillation/flutter. The revised PRECISION-AF target population, patients with recent atrial fibrillation and heart failure with mid-range and preserved ejection fractions, is an underserved population and we believe our Phase 2B data indicates that Gencaro may have a positive impact for these patients.”

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 April 2019, GENETIC-AF Phase 2B clinical trial results were published in the Journal of the American College of Cardiology: Heart Failure in the paper “GENETIC-AF: Bucindolol for the Maintenance of Sinus Rhythm in a Genotype-Defined Heart Failure Population”.
- 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 injection fractions (LVEF) $\geq 40\%$ and $\leq 55\%$. Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF in the first quarter of 2020.

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 continued in the second quarter.
- Subject to securing additional financing, IND-enabling non-clinical studies are anticipated to begin in the fourth quarter of 2019, and an IND submission is anticipated in the second half of 2020.

Second Quarter 2019 Summary Financial Results

Cash and cash equivalents were \$9.97 million as of June 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, through the first quarter of 2020.

Research and development (R&D) expenses for the three months ended June 30, 2019 were \$0.4 million compared to \$1.2 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.

General and administrative (G&A) expenses for the three months ended June 30, 2019 were \$1.1 million, compared to \$1.0 million in the second quarter of 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 June 30, 2019 were \$1.5 million compared to \$2.2 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 \$1.4 million, or \$1.14 per share, for the second quarter of 2019 compared to \$2.1 million, or \$2.74 per share, for the second 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 (PAD). 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 first 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>June 30, 2019</u>	<u>December 31, 2018</u>
Cash and cash equivalents	\$9,966	\$6,608
Working capital	\$9,124	\$5,984
Total assets	\$10,388	\$6,825
Total stockholders' equity	\$9,189	\$6,032

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

Three Months Ended Six Months Ended

June 30, June 30,

2019 2018 2019 2018

(in thousands, except share and per share amounts)

Costs and expenses:				
Research and development	\$ 440	\$ 1,154	\$ 1,102	\$ 2,874
General and administrative	1,068	1,002	2,187	2,055
Total costs and expenses	1,508	2,156	3,289	4,929
Loss from operations	(1,508)	(2,156)	(3,289)	(4,929)
Interest and other income	48	43	86	84
Interest expense	(3)	(3)	(6)	(6)
Loss before income taxes	(1,463)	(2,116)	(3,209)	(4,851)
Income tax benefit	27	—	109	—
Net loss	<u>\$ (1,436)</u>	<u>\$ (2,116)</u>	<u>\$ (3,100)</u>	<u>\$ (4,851)</u>
Change in unrealized loss on marketable securities	—	—	—	2
Comprehensive loss	<u>\$ (1,436)</u>	<u>\$ (2,116)</u>	<u>\$ (3,100)</u>	<u>\$ (4,849)</u>
Net loss per share:				
Basic and diluted	\$ (1.14)	\$ (2.74)	\$ (2.87)	\$ (6.34)
Weighted average shares outstanding:				
Basic and diluted	1,263,768	773,528	1,080,885	765,164