



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

Westminster, CO, May 8, 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 March 31, 2019 and provided a corporate update.

“In the first part of this year, we continued to make progress on our lead development program Gencaro, achieving an agreement with the FDA on our Special Protocol Assessment for the PRECISION-AF Phase 3 clinical trial evaluating Gencaro as potentially the first genetically-targeted treatment for atrial fibrillation,” commented [Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer. “Importantly, the GENETIC-AF Phase 2B clinical trial results, which are guiding our Phase 3 development, were accepted and published in JACC: Heart Failure.”

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 February 2019, ARCA received a *Special Protocol – 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. Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF by the end of 2019.
- 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”.

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

First Quarter 2019 Summary Financial Results

Cash, cash equivalents and marketable securities were \$8.0 million as of March 31, 2019, compared to \$6.6 million as of December 31, 2018. 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 third quarter of 2019.

Research and development (R&D) expenses for the three months ended March 31, 2019 were \$0.7 million compared to \$1.7 million for the corresponding period of 2018. The \$1.1 million 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 March 31, 2019 were \$1.1 million similar to \$1.1 million in the first 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 our ongoing operations.

Total operating expenses for the three months ended March 31, 2019 were \$1.8 million compared to \$2.8 million for the corresponding period of 2018. The decrease in total operating expenses was primarily due to the decrease in R&D expense due to the completion of the GENETIC-AF clinical trial.

Net loss was \$1.7 million, or \$1.86 per share, for the first quarter of 2019 compared to \$2.7 million, or \$3.61 per share, for the first quarter of 2018.

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

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 patients with heart failure. 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 third 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 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>March 31, 2019</u>	<u>December 31, 2018</u>
Cash and cash equivalents	\$8,006	\$6,608
Working capital	\$7,231	\$5,984
Total assets	\$8,606	\$6,825
Total stockholders' equity	\$7,318	\$6,032

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended	
	March 31,	
	2019	2018
	(in thousands, except share and per share amounts)	
Costs and expenses:		
Research and development	\$ 662	\$ 1,720
General and administrative	1,119	1,053
Total costs and expenses	1,781	2,773
Loss from operations	(1,781)	(2,773)
Interest and other income	38	41
Interest expense	(3)	(3)
Loss before income taxes	(1,746)	(2,735)
Income tax benefit	82	—
Net loss	<u>\$ (1,664)</u>	<u>\$ (2,735)</u>
Change in unrealized loss on marketable securities	—	2
Comprehensive loss	<u>\$ (1,664)</u>	<u>\$ (2,733)</u>
Net loss per share:		
Basic and diluted	\$ (1.86)	\$ (3.61)
Weighted average shares outstanding:		
Basic and diluted	895,970	756,706