



ARCA BIOPHARMA ANNOUNCES FISCAL YEAR 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Initiation of Pivotal Phase 3 PRECISION-AF Clinical Trial Anticipated in Fourth Quarter

Westminster, CO, February 27, 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 year ended December 31, 2018 and provided a corporate update.

“During 2018, we continued to make progress on our lead development program as we: reported Phase 2B results for the GENETIC-AF trial; designed a Phase 3 development plan based on learnings from those results; identified a clear regulatory path; and, began discussions with the FDA to confirm agreement on future development of Gencaro, potentially the first genetically-targeted cardiovascular therapeutic,” commented Dr. Michael Bristow, ARCA’s President and Chief Executive Officer. “With the Gencaro FDA SPA agreement now in place, 2019 will be an important year for ARCA as we work towards the initiation of the Phase 3 clinical trial and expand development activities for AB171, a potential genetically-targeted treatment for heart failure and peripheral arterial disease.”

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.
 - PRECISION-AF is designed as a double-blind, active-controlled, multicenter, international study comparing Gencaro with Toprol-XL (metoprolol succinate) for the prevention of AF recurrence or all-cause mortality (ACM) in HF patients with mid-range ejection fraction (HFmrEF).
 - Subject to securing additional financing, ARCA anticipates initiating PRECISION-AF in the fourth quarter of 2019.

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 were continued in the fourth quarter.
- IND-enabling non-clinical studies are anticipated to begin in the second half of 2019.
- IND submission anticipated in the first quarter of 2020.

2018 Summary Financial Results

Cash, cash equivalents and marketable securities were \$6.6 million as of December 31, 2018, compared to \$11.8 million as of December 31, 2017. 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 year ended December 31, 2018 were \$4.2 million compared to \$14.1 million for 2017. The \$9.8 million decrease in R&D expenses in 2018 as compared to 2017 was primarily due to decreased clinical expenses following the completion of the GENETIC-AF clinical trial in 2017.

General and administrative (G&A) expenses for the year ended December 31, 2018 were \$3.9 million compared to \$4.6 million in 2017. 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 2018 were \$8.1 million compared to \$18.7 million during 2017. The decrease in total operating expenses in 2018 was primarily due to the decrease in R&D expense due to the completion of the GENETIC-AF clinical trial.

Net loss was \$7.9 million, or \$0.57 per share, for 2018 compared to \$18.5 million, or \$1.77 per share, for 2017.

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 with mid-range ejection fraction. 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.

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 second 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, 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)

ARCA BIOPHARMA, INC.

BALANCE SHEET DATA
(in thousands)
(unaudited)

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Cash, cash equivalents & marketable securities	\$6,608	\$11,752
Working capital	\$5,984	\$10,229
Total assets	\$6,825	\$12,365
Total stockholders' equity	\$6,032	\$10,275

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	<u>Years Ended December 31,</u>	
	2018	2017
	<small>(in thousands, except share and per share amounts)</small>	
Costs and expenses:		
Research and development	\$ 4,239	\$ 14,076
General and administrative	3,879	4,636
Total costs and expenses	8,118	18,712
Loss from operations	(8,118)	(18,712)
Interest and other income	162	167
Interest expense	(8)	(6)
Loss before income taxes	(7,964)	(18,551)
Income tax benefit	31	61
Net loss	<u>\$ (7,933)</u>	<u>\$ (18,490)</u>
Change in unrealized loss on marketable securities	2	17
Comprehensive loss	<u>\$ (7,931)</u>	<u>\$ (18,473)</u>
Net loss per share:		
Basic and diluted	\$ (0.57)	\$ (1.77)
Weighted average shares outstanding:		
Basic and diluted	13,849,055	10,431,391