ARCA biopharma Announces Second Quarter 2021 Financial Results and Provides Corporate Update

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- ***Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for COVID-19 expanded to South America***
- ***Topline data anticipated in the fourth quarter of 2021***

Westminster, CO, August 4, 2021 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today reported second quarter 2021 financial results and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "We continue to be encouraged with the opportunities we see in our development pipeline compounds, rNAPc2 and Gencaro. With the ASPEN-COVID-19 Phase 2b trial of rNAPc2 expanding to South America, we look forward to completing the trial and we anticipate sharing the results in the fourth quarter. Given the rate of global vaccination and the continued emergence of variants, along with rNAPc2's combination of anticoagulant, anti-inflammatory and antiviral properties, we believe it has the potential to be effective in addressing COVID-19 impacts in hospitalized patients. For Gencaro, we believe that, if approved, it may be a safe and effective therapy for the treatment of higher ejection fraction heart failure patients with atrial fibrillation and look forward to evaluating it in the planned PRECISION-AF Phase 3 clinical study."

Pipeline Update

rNAPc2 (AB201) – a small recombinant protein being developed as a potential treatment for RNA virus associated disease, initially focusing on COVID-19.

- On-going Phase 2b clinical trial (ASPEN-COVID-19) evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19.
- ASPEN-COVID-19 expanding to South America with regulatory clinical trial commencement authorizations in Argentina and Brazil.
- Phase 2b topline data anticipated in the fourth quarter of 2021.
- In July, the Company entered into a patent assignment agreement with the University Medical Center of Johannes Gutenberg University Mainz, Germany, under which ARCA received exclusive world-wide patent rights related to the use of rNAPc2 as a potential

treatment for COVID-19, and other potential indications.

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).

- Gencaro Phase 2b data on AF burden and rhythm control interventions was published in *Circulation: Arrhythmia and Electrophysiology*, a journal of the American Heart Association. In the Phase 2b superiority clinical trial, although the prespecified primary endpoint was not met, compared with metoprolol, Gencaro reduced AF burden, delayed AF progression, increased maintenance of sinus rhythm, and reduced the need for additional rhythm control interventions in patients with HF and the genotype which responds most favorably to Gencaro.

- ARCA currently has an agreement with the U.S. FDA, known as a Special Protocol Assessment, or SPA, for the requirements of a Gencaro Phase 3 clinical trial, PRECISION-AF, that would support potential approval of Gencaro if successful. The Company is currently evaluating the potential timing for initiation of PRECISION-AF relative to the COVID-19 pandemic and the ability to recruit patients for a cardiovascular clinical trial, and based on an improving clinical trial ecosystem, has begun organizing necessary trial logistics.

Corporate

- The Company added to its executive team with the hiring of Jeff Dekker as Chief Financial Officer and Christopher Graybill as Vice President, Clinical Development.

Second Quarter 2021 Summary Financial Results

Cash and cash equivalents were $63.2 million as of June 30, 2021, compared to $49.1 million as of December 31, 2020. ARCA believes that its current cash and cash equivalents will be sufficient to fund its operations through 2022.

Research and development (R&D) expenses were $3.6 million for the quarter ended June 30, 2021, compared to $0.4 million for the corresponding period in 2020. The $3.2 million increase in R&D expenses in the second quarter was primarily related to the initiation of the rNAPc2 clinical trial in the second half of 2020. R&D expenses in 2021 are expected to be higher than 2020, as the Company continues the rNAPc2 Phase 2b clinical trial.

General and administrative (G&A) expenses were $1.3 million for the quarter ended June 30, 2021, compared to $0.9 million for the corresponding period in 2020. The $0.3 million increase in G&A expenses was primarily a result of higher personnel costs in 2021. G&A expenses in the second half of 2021 are expected to be consistent with the first half of 2021 as the Company maintains administrative activities to support its ongoing operations.

Total operating expenses for the quarter ended June 30, 2021 were $4.8 million compared to $1.3 million for the second quarter of 2020.

Net loss for the quarter ended June 30, 2021 was $4.8 million, or $0.34 per basic and diluted share, compared to $1.3 million, or $0.73 per basic and diluted share for the second quarter of 2020.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically targeted therapies for cardiovascular diseases through a precision medicine approach to drug development. ARCA is developing rNAPc2 as a potential treatment for diseases caused by RNA viruses, initially focusing on COVID-19. The U.S. FDA has granted Fast Track designation to the rNAPc2 development program, currently in Phase 2 clinical testing. ARCA is also developing Gencaro™ (bucindolol hydrochloride), an investigational, pharmacologically unique beta-blocker and mild vasodilator, as a potential treatment for 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 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 potential future development plans for rNAPc2 and Gencaro, the expected features and characteristics of rNAPc2 and Gencaro, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, rNAPc2's potential to treat COVID-19, future treatment options for patients with COVID-19 or AF, the potential for Gencaro to be the first genetically targeted AF prevention treatment and the ability of ARCA's financial resources to support its operations through 2022. 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 rNAPc2 or 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, 2020, 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$63,197	$49,071
Working capital	$61,098	$46,469
Total assets	$65,338	$50,429
Total stockholders' equity	$61,208	$46,521

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
	(in thousands, except share and per share amounts)			
Costs and expenses:				
Research and development	$ 3,577	$ 372	$ 6,453	$ 737
General and administrative	1,260	938	2,486	1,913
Total costs and expenses	4,837	1,310	8,939	2,650
Loss from operations	(4,837)	(1,310)	(8,939)	(2,650)
Interest and other income	3	2	5	26
Interest expense	—	(3)	—	(7)
Loss before income taxes	(4,834)	(1,311)	(8,934)	(2,631)
Income tax benefit	—	9	—	9
Net loss	$ (4,834)	$ (1,302)	$ (8,934)	$ (2,622)
Net loss per share:				
Basic and diluted	$ (0.34)	$ (0.73)	$ (0.67)	$ (1.55)
Weighted average shares outstanding:				
Basic and diluted	14,410,143	1,793,900	13,389,207	1,693,985