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

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- ***Topline data from Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for COVID-19 anticipated in the third quarter of 2021***

Westminster, CO, May 11, 2021 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today reported first quarter 2021 financial results and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "We are continuing to advance the Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19, actively enrolling patients at 7 clinical trial sites in the United States. We look forward to sharing the trial results early in the third quarter of this year. We believe rNAPc2's combination of anticoagulant, anti-inflammatory and antiviral properties, give it the potential to be effective in addressing the impact of COVID-19 from multiple pathways. As a therapeutic aimed at a host response to a disease syndrome, we believe rNAPc2 has therapeutic potential for future viral outbreaks beyond the current pandemic, even after safe and effective vaccines for SARS-CoV-2 are successfully deployed."

Pipeline Update

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

- Phase 2b clinical trial (ASPEN-COVID-19) evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19 initiated in December 2020.
- Currently enrolling patients in ASPEN-COVID-19 at 7 clinical trial sites in the United States.
- Phase 2b topline data anticipated early in the third quarter of 2021.
- U.S. Food and Drug Administration (FDA) designated the investigation of rNAPc2 as a potential treatment for COVID-19 as a Fast Track development program.

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).

- In February 2021, ARCA was issued a new patent by the United States Patent and Trademark Office (USPTO) for use of Gencaro in treating AF in patients with HF. The Company believes this patent would provide effective patent coverage in the United States into 2039. ARCA has filed similar patent applications in other countries.

- The Company continues to evaluate 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.

First Quarter 2021 Summary Financial Results

Cash and cash equivalents were $66.9 million as of March 31, 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 $2.9 million for the quarter ended March 31, 2021, compared to $0.4 million for the corresponding period in 2020. The $2.5 million increase in R&D expenses in the first 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 $1.2 million for the quarter ended March 31, 2021, compared to $1.0 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 2021 are expected to be consistent with those in 2020 as the Company maintains administrative activities to support its ongoing operations.

Total operating expenses for the quarter ended March 31, 2021 were $4.1 million compared to $1.3 million for the first quarter of 2020.

Net loss for the quarter ended March 31, 2021 was $4.1 million, or $0.33 per basic and diluted share, compared to $1.3 million, or $0.83 per basic and diluted share for the first 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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ARCA BIOPHARMA, INC.

BALANCE SHEET DATA
(in thousands)
(unaudited)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$66,933	$49,071
Working capital	$65,850	$46,469
Total assets	$69,183	$50,429
Total stockholders' equity	$65,909	$46,521

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
	(in thousands, except share and per share amounts)	
Costs and expenses:		
Research and development	$ 2,876	$ 365
General and administrative	1,226	975
Total costs and expenses	4,102	1,340
Loss from operations	(4,102)	(1,340)
Interest and other income	2	24
Interest expense	—	(4)
Net loss	$ (4,100)	$ (1,320)
Net loss per share:		
Basic and diluted	$ (0.33)	$ (0.83)
Weighted average shares outstanding:		
Basic and diluted	12,356,928	1,594,070