ARCA biopharma Announces 2020 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***
- ***New patent issued by USPTO for use of Gencaro in treating atrial fibrillation in heart failure patients with ejection fractions greater than 40%***

Westminster, CO, March 18, 2021 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today reported 2020 financial results and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "We are currently actively enrolling patients in a Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19 who are at high risk for thrombotic complications, as indicated by elevated D-dimer levels, which are elevated in nearly 70% of hospitalized COVID-19 patients and are associated with adverse clinical outcomes. 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. We look forward to sharing the trial results in the third quarter of this year. 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 evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19 initiated in December 2020.
- Phase 2b topline data anticipated 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 the HF population that ARCA plans to enroll in Phase 3 development, a population that includes more than half of all HF patients in the United States and Europe and has few approved or effective drug therapies. 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 FDA has issued a Special Protocol Assessment (SPA) agreement for a single Phase 3 clinical trial (PRECISION-AF) to examine Gencaro as a genetically targeted therapy for the prevention of AF recurrence in certain heart failure patients. We continue to evaluate the feasibility and potential timing for initiation of PRECISION-AF relative to the COVID-19 pandemic and the ability to recruit patients for a cardiovascular clinical trial.

Full Year 2020 Summary Financial Results

Cash and cash equivalents were $49.1 million as of December 31, 2020, compared to $8.4 million as of December 31, 2019. ARCA believes that its current cash and cash equivalents, together with the $23.3 million of net proceeds raised through February 2021 from sales of the common stock under the Company's "at-the-market" offering, will be sufficient to fund its operations through 2022.

Research and development (R&D) expenses were $5.0 million for the year ended December 31, 2020, compared to $1.8 million for 2019. The $3.2 million increase in R&D expenses in 2020 as compared to 2019 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 $4.8 million for the year ended December 31, 2020, compared to $4.0 million for 2019, an increase of approximately $0.8 million. The increase in expenses during 2020 was comprised primarily of increased legal and professional costs, insurance costs and higher personnel costs in 2020, as compared to 2019. G&A expenses in 2021 are expected to be consistent with those in 2020 as the Company maintains administrative activities to support our ongoing operations.

Total operating expenses for the year ended December 31, 2020 were $9.8 million compared to $5.8 million in 2019.

Net loss for the year ended December 31, 2020 was $9.7 million, or $2.07 per basic and diluted share, compared to $5.5 million, or $4.15 per basic and diluted share in 2019.

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)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$49,071	$8,363
Working capital	$46,469	$7,554
Total assets	$50,429	$8,536
Total stockholders' equity	$46,521	$7,610

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Years Ended December 31,	
	2020	**2019**
	(in thousands, except share and per share amounts)	
Costs and expenses:		
Research and development	$ 4,992	$ 1,833
General and administrative	4,774	3,981
Total costs and expenses	9,766	5,814
Loss from operations	(9,766)	(5,814)
Interest and other income	28	172
Interest expense	(9)	(7)
Loss before income taxes	(9,747)	(5,649)
Income tax benefit	9	167
Net loss	$ (9,738)	$ (5,482)
Net loss per share:		
Basic and diluted	$ (2.07)	$ (4.15)
Weighted average shares outstanding:		
Basic and diluted	4,710,237	1,321,234