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

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- ***On-going Phase 2b clinical trial (ASPEN-COVID-19) evaluating rNAPc2 as a potential treatment for COVID-19***
- ***DSMC interim analysis of safety and efficacy data from ASPEN-COVID-19 completed with recommendation to continue trial to completion with no modifications***
- ***Topline data anticipated in first quarter of 2022***
- ***Cash and cash equivalents of $58.3 million at September 30, 2021, sufficient to fund operations through 2022***

Westminster, CO, November 2, 2021 – ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today reported third quarter 2021 financial results and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "The continuing pandemic and the emergence of multiple variants that have led to a resurgence of infections and hospitalizations, highlight the need for additional safe and effective therapeutic tools to treat patients that develop severe COVID-19. With rNAPc2's combination of anticoagulant, anti-inflammatory and potential antiviral properties, we believe it has the potential to be effective in addressing COVID-19 impacts in hospitalized patients. Our international Phase 2b clinical trial is nearing completion and we look forward to sharing its results in the first quarter."

Pipeline Update

rNAPc2 (AB201) – a small recombinant protein being developed as a potential treatment for COVID-19 and potentially other viral diseases.

- On-going Phase 2b clinical trial (ASPEN-COVID-19) evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19, enrolling patients at investigative sites in United States, Argentina and Brazil.

- Clinical trial Data and Safety Monitoring Committee (DSMC) completed a pre-specified interim analysis and, based on the DSMC's review of approximately 75% of the projected final efficacy and safety data, recommended completion of the clinical trial with no modifications to the clinical trial design.

- Phase 2b topline data anticipated in first quarter of 2022.

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).

- 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.

Third Quarter 2021 Summary Financial Results

Cash and cash equivalents were $58.3 million as of September 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 $3.4 million for the quarter ended September 30, 2021, compared to $1.1 million for the corresponding period in 2020. The $2.3 million increase in R&D expenses in the third 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 September 30, 2021, compared to $0.9 million for the corresponding period in 2020. The $0.4 million increase in G&A expenses was primarily a result of higher personnel costs in 2021. G&A expenses in the last quarter of 2021 are expected to be consistent with the third quarter of 2021 as the Company maintains administrative activities to support its ongoing operations.

Total operating expenses for the quarter ended September 30, 2021 were $4.7 million compared to $2.0 million for the third quarter of 2020.

Net loss for the quarter ended September 30, 2021 was $4.7 million, or $0.33 per basic and diluted share, compared to $2.0 million, or $0.33 per basic and diluted share for the third 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 COVID-19 and potentially other viral diseases. 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)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$58,313	$49,071
Working capital	$56,484	$46,469
Total assets	$60,192	$50,429
Total stockholders' equity	$56,600	$46,521

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
	(in thousands, except share and per share amounts)			
Costs and expenses:				
Research and development	$ 3,438	$ 1,051	$ 9,891	$ 1,788
General and administrative	1,278	939	3,764	2,852
Total costs and expenses	4,716	1,990	13,655	4,640
Loss from operations	(4,716)	(1,990)	(13,655)	(4,640)
Interest and other income	4	1	9	27
Interest expense	—	(2)	—	(9)
Loss before income taxes	(4,712)	(1,991)	(13,646)	(4,622)
Income tax benefit	—	—	—	9
Net loss	$ (4,712)	$ (1,991)	$ (13,646)	$ (4,613)
Net loss per share:				
Basic and diluted	$ (0.33)	$ (0.33)	$ (0.99)	$ (1.46)
Weighted average shares outstanding:				
Basic and diluted	14,410,143	6,044,315	13,733,259	3,154,680