ARCA biopharma Announces Third Quarter 2020 Financial Results and Provides Corporate Update

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- ***Initiation of Phase 2b clinical trial evaluating AB201 as a potential treatment for COVID-19 anticipated in fourth quarter***
- ***Topline data from trial anticipated Q2 2021***

Westminster, CO, November 2, 2020 – 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 third quarter of 2020 and provided a corporate update.

Dr. Michael Bristow, ARCA's President and Chief Executive Officer, commented, "With the resurgence of SARS-CoV-2 across the country and around the globe, the need for effective therapies to treat patients hospitalized with COVID-19 remains an urgent priority. AB201'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 are working rapidly towards initiating the Phase 2b clinical trial evaluating AB201 as a potential treatment for COVID-19."

Pipeline Update

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

- Advancing development of AB201 as a potential treatment for patients hospitalized with COVID-19
- U.S. Food and Drug Administration (FDA) approved the Investigational New Drug (IND) application for AB201 as a potential treatment for COVID-19
- ARCA estimates initiating Phase 2b clinical testing of AB201 in fourth quarter of this year

Gencaro™ (bucindolol hydrochloride) is 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). 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. Initiation of the PRECISION-AF Phase 3 clinical trial is on hold due to the ongoing COVID-19 pandemic and prioritizing the development of AB201. Future development of Gencaro, including initiating any Phase 3 clinical trial, is dependent on obtaining additional financing.

Third Quarter 2020 Summary Financial Results

Cash and cash equivalents were $51.1 million as of September 30, 2020, compared to $8.4 million as of December 31, 2019. ARCA believes that its current cash and cash equivalents will be sufficient to fund its operations through 2022, including the projected costs for the AB201 Phase 2b clinical trial.

Research and development (R&D) expense for the three months ended September 30, 2020 was $1.1 million compared to $0.3 million for the corresponding period of 2019, an increase of $0.7 million. R&D expense for the nine months ended September 30, 2020 was $1.8 million compared to $1.4 million for the corresponding period of 2019, an increase of approximately $0.3 million.

Clinical expense increased approximately $0.3 million for the three and nine months ended September 30, 2020, as compared to the corresponding periods of 2019. Manufacturing process development costs increased approximately $0.2 million for the three and nine months ended September 30, 2020, as compared to the corresponding periods of 2019. The increase in costs were related to initial costs for the AB201 clinical trial, which the Company plans to initiate in the fourth quarter of 2020. The remaining increase is primarily a result of higher outside services and consulting costs.

General and administrative (G&A) expenses were $0.9 million for both the three months ended September 30, 2020 and 2019. G&A expenses were $2.9 million and $3.1 million for the nine months ended September 30, 2020 and 2019, respectively. The $0.2 million decrease was primarily a result of lower personnel costs and lower outside services and consulting costs in 2020.

Total operating expenses for the three months ended September 30, 2020 were $1.9 million compared to $1.2 million for the corresponding period in 2019. Total operating expenses for the nine months ended September 30, 2020 were $4.6 million compared to $4.5 million for the corresponding period in 2019.

Net loss for the three months ended September 30, 2020 was $2.0 million, or $0.33 per basic and diluted share, compared to $1.2 million, or $0.76 per basic and diluted share, for the corresponding period in 2019. Net loss for the nine months ended September 30, 2020 was $4.6 million, or $1.46 per basic and diluted share, compared to $4.3 million, or $3.46 per basic and diluted share, for the corresponding period 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 AB201 as a potential treatment for diseases caused by RNA viruses, initially focusing on COVID-19. 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 AB201 and Gencaro, the expected features and characteristics of AB201 and Gencaro, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, AB201'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 AB201 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, 2019, 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, 2020	December 31, 2019
Cash and cash equivalents	$51,095	$8,363
Working capital	$50,409	$7,554
Total assets	$51,982	$8,536
Total stockholders' equity	$50,455	$7,610

ARCA BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
	(in thousands, except share and per share amounts)			
Costs and expenses:				
Research and development	$ 1,051	$ 347	$ 1,788	$ 1,449
General and administrative	939	900	2,852	3,087
Total costs and expenses	1,990	1,247	4,640	4,536
Loss from operations	(1,990)	(1,247)	(4,640)	(4,536)
Interest and other income	1	50	27	136
Interest expense	(2)	(1)	(9)	(7)
Loss before income taxes	(1,991)	(1,198)	(4,622)	(4,407)
Income tax benefit	—	42	9	151
Net loss	$ (1,991)	$ (1,156)	$ (4,613)	$ (4,256)
Net loss per share:				
Basic and diluted	$ (0.33)	$ (0.76)	$ (1.46)	$ (3.46)
Weighted average shares outstanding:				
Basic and diluted	6,044,315	1,521,259	3,154,680	1,229,289