



## ARCA BIOPHARMA ANNOUNCES SECOND QUARTER 2020 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- *AB201 being developed as a potential treatment for COVID-19 and other RNA virus associated diseases*
- *ARCA anticipates filing an IND for AB201 in Q3 2020 and initiating Phase 2 clinical testing in Q4 2020*

Westminster, CO, August 5, 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 second quarter of 2020 and provided a corporate update.

[Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer, commented, “As the SARS-CoV-2 pandemic has progressed, serious complications relating to over-activation of the coagulation and immune systems have increasingly been observed in patients hospitalized with severe disease. Based on previous and emerging work on mechanisms of virus pathogenesis, we believe this evidence implicates involvement of tissue factor pathways, of which AB201 is a potent and long-acting inhibitor, providing a strong rationale to evaluate AB201 as a potential therapeutic for COVID-19. With this rationale along with significant safety data from prior human clinical trials, we look forward to initiating Phase 2 clinical development later this year.”

### Pipeline Update

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

- Initiated planning for development of AB201 as a potential treatment for patients with severe COVID-19.
- Clinical collaboration established with the Colorado Prevention Center, the University of Colorado's Academic Research Organization.
- The Company anticipates filing an Investigational New Drug (IND) application for AB201 as a potential treatment for COVID-19 with the U.S. Food and Drug Administration (FDA) in third quarter of this year.
- Pending FDA concurrence, ARCA estimates initiating Phase 2 clinical testing of AB201 in the fourth quarter of this year.

**Gencaro**<sup>TM</sup> (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).

- 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. ARCA estimates that enrollment in PRECISION-AF could start in 2021; however, this estimate is subject to change due to the uncertainties of the ongoing COVID-19 pandemic and the availability of patients for non-COVID-19 related clinical trials. Any future development of Gencaro, including initiating any Phase 3 clinical trial, is dependent on obtaining additional financing.
- 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.

## **Second Quarter 2020 Summary Financial Results**

**Cash and cash equivalents** were \$11.0 million as of June 30, 2020, compared to \$8.4 million as of December 31, 2019. ARCA believes that its current cash and cash equivalents, together with net proceeds of \$24.1 million raised in July from sales of its common stock, will be sufficient to fund its operations, at its current cost structure, plus projected costs for the AB201 clinical development program, through the end of the fourth quarter of 2021.

**Research and development (R&D) expense** for the three months ended June 30, 2020 was \$0.4 million compared to \$0.4 million for the corresponding period of 2019, a decrease of approximately \$68,000. R&D expense for the six months ended June 30, 2020 was \$0.7 million compared to \$1.1 million for the corresponding period of 2019, a decrease of approximately \$0.4 million.

R&D personnel costs decreased approximately \$0.1 million for the three months ended June 30, 2020, as compared to the corresponding period of 2019. R&D personnel costs decreased approximately \$0.3 million for the six months ended June 30, 2020, as compared to the corresponding period of 2019. The remaining decrease is primarily a result of lower outside services and consulting costs.

**General and administrative (G&A) expenses** were \$0.9 million and \$1.1 million for the three months ended June 30, 2020 and 2019, respectively. The \$0.1 million decrease was primarily a result of lower personnel costs and lower outside services and consulting costs in 2020. G&A expenses were \$1.9 million and \$2.2 million for the six months ended June 30, 2020 and 2019, respectively. The \$0.3 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 June 30, 2020 were \$1.3 million compared to \$1.5 million for the corresponding period in 2019. Total operating expenses for the six months

ended June 30, 2020 were \$2.7 million compared to \$3.3 million for the corresponding period in 2019.

**Net loss** for the three months ended June 30, 2020 was \$1.3 million, or \$0.73 per basic and diluted share, compared to \$1.4 million, or \$1.14 per basic and diluted share, for the corresponding period in 2019. Net loss for the six months ended June 30, 2020 was \$2.6 million, or \$1.55 per basic and diluted share, compared to \$3.1 million, or \$2.87 per basic and diluted share, for the corresponding period in 2019.

The Company will need to raise additional capital, and/or complete a partnership or other possible strategic transaction, to fund future operations and develop AB201 and Gencaro or any other product candidates.

### **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](http://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 ability of ARCA's financial resources to support its operations through the end of the fourth quarter of 2021, 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 or CAC, future treatment options for patients with COVID-19, or AF, and the potential for Gencaro to be the first genetically targeted AF prevention treatment. 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.*

**Investor & Media Contact:**

Derek Cole

720.940.2163

[derek.cole@arcabio.com](mailto:derek.cole@arcabio.com)

(Tables follow)

###

**ARCA BIOPHARMA, INC.**

**BALANCE SHEET DATA**

(in thousands)

(unaudited)

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$11,041	\$8,363
Working capital	\$10,245	\$7,554
Total assets	\$11,633	\$8,536
Total stockholders' equity	\$10,305	\$7,610

**ARCA BIOPHARMA, INC.**

**STATEMENTS OF OPERATIONS**

(unaudited)

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>

(in thousands, except share and per share amounts)

Costs and expenses:

Research and development	\$ 372	\$ 440	\$ 737	\$ 1,102
General and administrative	938	1,068	1,913	2,187
Total costs and expenses	<u>1,310</u>	<u>1,508</u>	<u>2,650</u>	<u>3,289</u>
Loss from operations	<u>(1,310)</u>	<u>(1,508)</u>	<u>(2,650)</u>	<u>(3,289)</u>
Interest and other income	2	48	26	86
Interest expense	<u>(3)</u>	<u>(3)</u>	<u>(7)</u>	<u>(6)</u>
Loss before income taxes	<u>(1,311)</u>	<u>(1,463)</u>	<u>(2,631)</u>	<u>(3,209)</u>
Income tax benefit	9	27	9	109
Net loss	<u>\$ (1,302)</u>	<u>\$ (1,436)</u>	<u>\$ (2,622)</u>	<u>\$ (3,100)</u>

Net loss per share:

Basic and diluted	\$ (0.73)	\$ (1.14)	\$ (1.55)	\$ (2.87)
-------------------	-----------	-----------	-----------	-----------

Weighted average shares outstanding:

Basic and diluted	1,793,900	1,263,768	1,693,985	1,080,885
-------------------	-----------	-----------	-----------	-----------