



## ARCA biopharma Announces 2021 Financial Results and Provides Corporate Update

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- *Topline data from Phase 2b ASPEN-COVID-19 clinical trial evaluating rNAPc2 as a potential treatment for COVID-19 anticipated in the last week of March 2022*

Westminster, CO, March 14, 2022 – [ARCA biopharma, Inc.](#) (Nasdaq: ABIO), a biopharmaceutical company applying a precision medicine approach to developing genetically targeted therapies for cardiovascular diseases, today reported 2021 financial results and provided a corporate update.

[Dr. Michael Bristow](#), ARCA’s President and Chief Executive Officer, commented, “We have completed blinded data collection from the Phase 2b clinical trial evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19 and look forward to unblinding and subsequently reporting results of the study in the last week of this month. We believe rNAPc2 has the potential to be effective in addressing the impact of COVID-19 from multiple pathways due to its combination of anticoagulant, anti-inflammatory and antiviral properties. We look forward to sharing the data with the FDA at an end of Phase 2 meeting.”

### Pipeline Update

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

- Topline data from Phase 2b ASPEN-COVID-19 clinical trial evaluating rNAPc2 as a potential treatment for patients hospitalized with COVID-19 anticipated in the last week of March 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).

- In January 2022, ARCA announced that the paper entitled “[Dose Limiting, Adverse Event Associated Bradycardia with  \$\beta\$ -blocker Treatment of Atrial Fibrillation in the GENETIC-AF Trial](#)” (William Abraham, et al) was published in [Heart Rhythm O<sup>2</sup>](#), a publication of the [Heart Rhythm Society](#). The paper details an analysis that examined the prevalence of bradycardia and its association with adverse events (AEs) and failure to achieve target dose in the GENETIC-AF [Phase 2b](#) clinical trial. In the genetically defined population of GENETIC-AF (all *ADRB1* Arg389Arg genotype), the prevalence of clinically important bradycardia was lower for Gencaro compared to metoprolol.

- The Company continues 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 2021 Summary Financial Results**

**Cash and cash equivalents** were \$53.4 million as of December 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 the middle of 2023.

**Research and development (R&D) expenses** were \$13.8 million for the year ended December 31, 2021, compared to \$5.0 million for 2020. The \$8.8 million increase in R&D expenses in 2021 as compared to 2020 was primarily related to the conduct of the rNAPc2 clinical trial. R&D expenses in 2022 are expected to be consistent with 2021.

**General and administrative (G&A) expenses** were \$5.5 million for the year ended December 31, 2021, compared to \$4.8 million for 2020, an increase of approximately \$0.7 million. The increase in expenses during 2021 was comprised primarily of increased personnel and insurance costs, offset by lower legal costs in 2021, as compared to 2020. G&A expenses in 2022 are expected to be consistent with those in 2021 as the Company maintains administrative activities to support our ongoing operations.

**Total operating expenses** for the year ended December 31, 2021 were \$19.3 million compared to \$9.8 million in 2020.

**Net loss** for the year ended December 31, 2021 was \$19.3 million, or \$1.39 per basic and diluted share, compared to \$9.7 million, or \$2.07 per basic and diluted share in 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](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 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 the middle of fiscal year 2023. 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, 2021, 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)**

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Cash and cash equivalents	\$53,359	\$49,071
Working capital	\$50,923	\$46,469
Total assets	\$54,924	\$50,429
Total stockholders' equity	\$51,043	\$46,521

**ARCA BIOPHARMA, INC.****STATEMENTS OF OPERATIONS****Years Ended December 31,****2021****2020****(in thousands, except share****and per share amounts)**

<b>Costs and expenses:</b>		
Research and development	\$ 13,832	\$ 4,992
General and administrative	5,503	4,774
Total costs and expenses	19,335	9,766
Loss from operations	(19,335)	(9,766)
Interest and other income	13	28
Interest expense	—	(9)
Loss before income taxes	(19,322)	(9,747)
Income tax benefit	—	9
Net loss	<u>\$ (19,322)</u>	<u>\$ (9,738)</u>
Net loss per share:		
Basic and diluted	\$ (1.39)	\$ (2.07)
Weighted average shares outstanding:		
Basic and diluted	13,903,871	4,710,237