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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of Earliest Event Reported): April 23, 2013**

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**ARCA biopharma, Inc.**  
(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-22873**  
(Commission  
File Number)

**36-3855489**  
(I.R.S. Employer  
Identification No.)

**8001 Arista Place, Suite 430, Broomfield, CO 80021**  
(Address of Principal Executive Offices) (Zip Code)

**(720) 940-2200**  
(Registrant's Telephone Number, Including Area Code)

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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## Section 7 - Regulation FD

### Item 7.01. Regulation FD Disclosure

ARCA biopharma, Inc. (the "Company" or "ARCA") intends to conduct meetings with potential investors on or after April 23, 2013 through June 1, 2013. ARCA expects to use the presentation materials furnished as Exhibit 99.1 hereto, in whole or in part and possibly with immaterial modifications, in connection with such meetings. The fact that these presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the presentation materials is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that it may make, by press release or otherwise, from time to time.

The text of the presentation materials attached to this report may omit various graphic images included in the actual presentation materials. The Company expects to make copies of the presentation materials, including such graphic images, available for viewing at the "Investor Relations" section of its website located at [www.arcabiopharma.com](http://www.arcabiopharma.com), although the Company reserves the right to discontinue that availability at any time.

The attached presentation materials contain "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 Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the potential for Gencaro to be an effective potential treatment for atrial fibrillation and the Company's ability to fund future operations. 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: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; the Company's ability to complete a strategic transaction to support the continued development Gencaro, and/or obtain additional financing; the Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the Company's ability to identify, develop and achieve commercial success for products and technologies; drug discovery and the regulatory approval process; estimated timelines for regulatory filings and the implications of interim or final results of the Company's clinical trials; the extent to which the Company's issued and pending patents may protect its products and technology; the potential of the Company's clinical development program to lead to the approval of the Company's New Drug Application for Gencaro; 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 SEC, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2012, the Company's Registration Statement on Form S-1 (Registration No. 333-187508), and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation dated April 23, 2013.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 23, 2013

**ARCA biopharma, Inc.**  
(Registrant)

By: /s/ Christopher D. Ozeroff  
Name: Christopher D. Ozeroff  
Title: SVP and General Counsel

INDEX TO EXHIBITS

Exhibit  
Number

Description

99.1

Presentation dated April 23, 2013.



T	T	C	C	A	G	G	G	T	C	T	C	C	T
A	A	G	G	T	C	C	C	T	G	C	C	G	A
T	T	C	C	A	G	C	G	T	C	G	G	C	T
A	A	G	G	T	C	G	C	T	G	C	C	G	A

# *Pioneering Genetically-Targeted Cardiovascular Therapies*

April 23, 2013

NASDAQ: ABIO

# Safe Harbor Statement

This presentation 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 Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the potential for Gencaro to be an effective potential treatment for atrial fibrillation and, the Company's ability to fund future operations. 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: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; the Company's ability to complete a strategic transaction to support the continued development Gencaro, and/or obtain additional financing; the Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the Company's ability to identify, develop and achieve commercial success for products and technologies; drug discovery and the regulatory approval process; estimated timelines for regulatory filings and the implications of interim or final results of the Company's clinical trials; the extent to which the Company's issued and pending patents may protect its products and technology; the potential of the Company's clinical development program to lead to the approval of the Company's New Drug Application for Gencaro; 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 SEC, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2012, the Company's Registration Statement on Form S-1 (Registration No. 333-187508), and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.



# Offering Summary

- Ticker Symbol ABIO
- Offering \$20,000,000  
Common stock + warrants
- Use of proceeds To fund Phase 2b development of Company's lead product candidate, Gencaro, working capital and general corporate purposes
- Placement agent Dawson James Securities, Inc.



# Corporate and Lead Product Highlights

- **Late stage cardiovascular company**
- **Pharmacogenomic drug development/personalized medicine approach**
  - Potentially first genetically-targeted cardiovascular drug
- **Experienced, successful management team**
- **Lead product Gencaro™ (bucindolol hydrochloride)**
  - 4<sup>th</sup> generation beta-blocker with extensive patient data
  - 1<sup>st</sup> potential indication - atrial fibrillation (AF)
- **Clearly defined regulatory pathway**
  - Similar endpoint basis for two most recent AF approvals
  - Beta blocker profile well characterized and understood
- **Significant market opportunities in a major unmet medical need<sup>1</sup>**
  - 2.7 million AF patients in U.S.; 250,000-500,000 new onset AF/year (2010)
  - Current therapies associated with adverse events
- **Robust IP portfolio**
  - US and EU market exclusivity, with potential patent extension, into 2029/2030

<sup>1</sup>Bristow MR, Aleong RG. JACC-Heart Fail 1:29-30, 2013

# ARCA biopharma *Leadership*

Michael R. Bristow, MD, PhD: *President/CEO*

Patrick Wheeler, *Chief Financial Officer*

Chris Ozeroff: *General Counsel*

Thomas Keuer: *EVP, Pharmaceutical Operations*

Monique Plamondon: *VP, Regulatory/Quality*



## **Board of Directors**

Michael R. Bristow, MD, PhD

Jean-Francois Formela, MD

Linda Grais, MD, JD (Lead Independent)

Burton E. Sobel, MD

John Zabriskie, PhD



5



# Pharmacogenomics: The science of personalized medicine

Personalized medicine refers to the tailoring of medical treatment to the individual genetic characteristics of each patient in order to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effect for those who will not.<sup>1</sup>

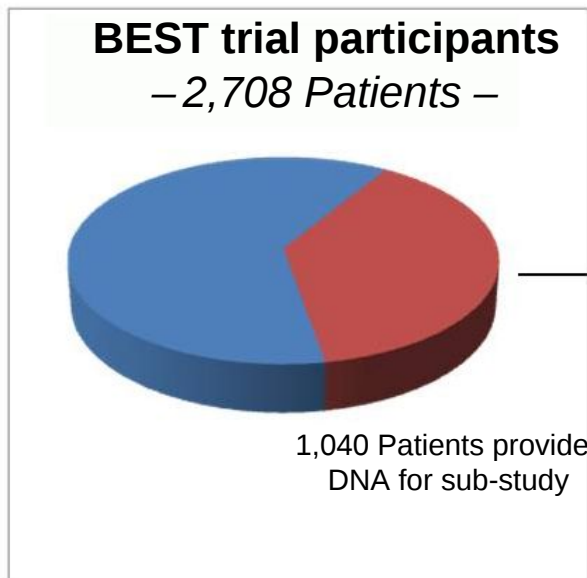
## **Potential Benefits**

- Better diagnoses and earlier intervention
- More efficient drug development
- More effective therapies
- Improved patient outcomes
- Reduced adverse drug reactions
- Reduced healthcare costs
- Extension of market exclusivity

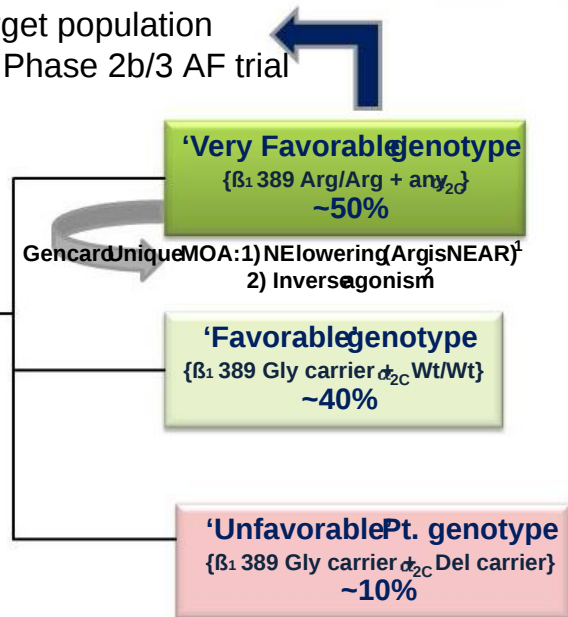
1 – President's Council of Advisors on Science and Technology, Priorities for Personalized Medicine, 2008

# Patient Population Genotypes

Results from Phase 3 BEST trial DNA sub-study, HF endpoint



Target population for Phase 2b/3 AF trial



Source: ARCA biopharma

<sup>1</sup>Liggett et al, PNAS 2006

<sup>2</sup>O'Connor et al, PLOS ONE 2012



# LabCorp Strategic Partnership

- ARCA has exclusive rights to Gencaro companion genetic test, has partnered with LabCorp
- Easy-to-administer, one-time genetic test that identifies genetic markers which predict clinical response
- Quick turnaround time for results



## Strategic Partner

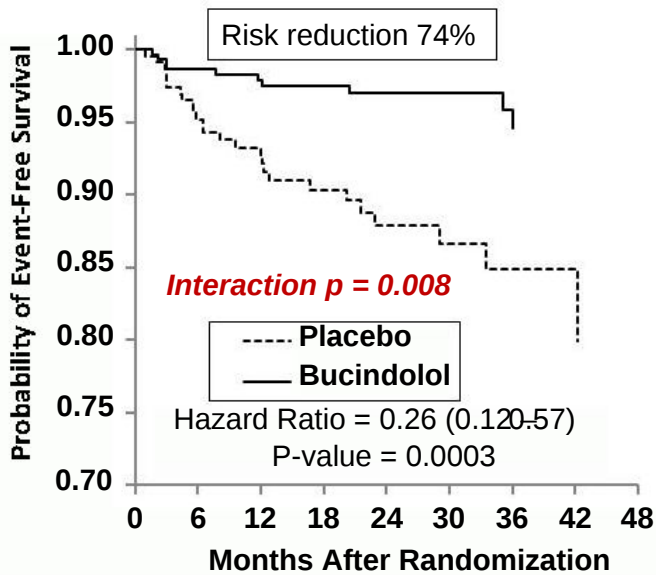
- S&P 500 Company
- \$5.7B in revenues in 2012
- 34,000 employees worldwide
- 220,000 clients
- Conducts over 1M tests daily



# Prevention of new onset AF in BEST by $\beta_1$ 389 Arg/Gly genotype

## BEST adrenergic receptor polymorphism substudy

$\beta_1$ 389 Arg/Arg (n = 441; 36 events)



Aleong et al, *Circulation* 124: A10438, 2011

In a meta-analysis of Phase 3 HF trials covering ~12,000 randomized patients, there was a 27% average reduction in incidence of new onset AF in heart failure where new onset AF was reported.<sup>1</sup>

1 - Abi Nasr I et al, *EJH* 28: 457-462, 2007

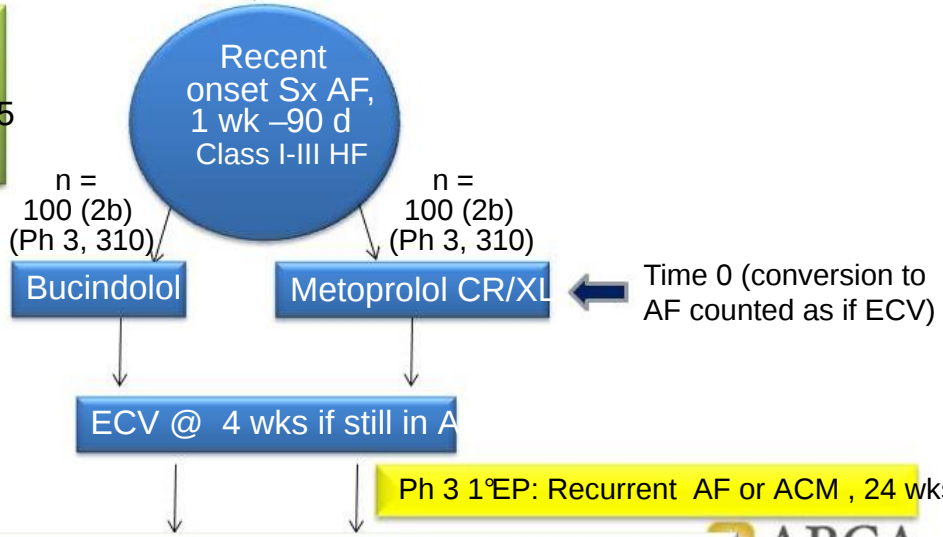


# Phase 2b → Ph 3 Adaptive Design Superiority Trial

Bucindolol vs. Metoprolol CR/XL, Prevention of Recurrent Atrial Fibrillation in Persistent AF HFREF Patients with the  $\beta_1$ 389 Arg/Arg Genotype post Electrical Cardioversion (ECV), + Adaptive Design to Phase 3

LVEF <0.50, Class II-III HF w/in 90 days  
No contra-indications to  $\beta$ -blockers  
 $\beta_1$ 389 Arg/Arg genotype

Projected timeline:  
Trial Initiation –Q4 2013  
Ph 2b Trial Data –Q4 2015  
Ph 3 Trial data Q4 2017



Phase 2b: 1<sup>st</sup> endpoint = recurrent AF or ACM, 24 weeks; 2<sup>nd</sup> endpoint = AF burden



# Strategic Partnership

- GENETIC-AF Clinical Trial Collaboration-



**Medtronic**

## Medtronic and ARCA have executed agreement to collaborate on GENETIC-AF

- Medtronic, Inc
  - World's largest medical technology company
  - Leader in medical technologies to improve the treatment of chronic diseases, including cardiac rhythm disorders
  - 45,000 employees
  - \$16 Billion –2012 Revenues
  - \$1.5 Billion –2012 Research & Development Investment
- Collaboration
  - Substudy of P2b portion of GENETIC-AF
  - Measure AF burden data by means of Medtronic continuous monitoring devices
  - Medtronic to provide support for AF burden substudy and for collection and analysis of substudy data



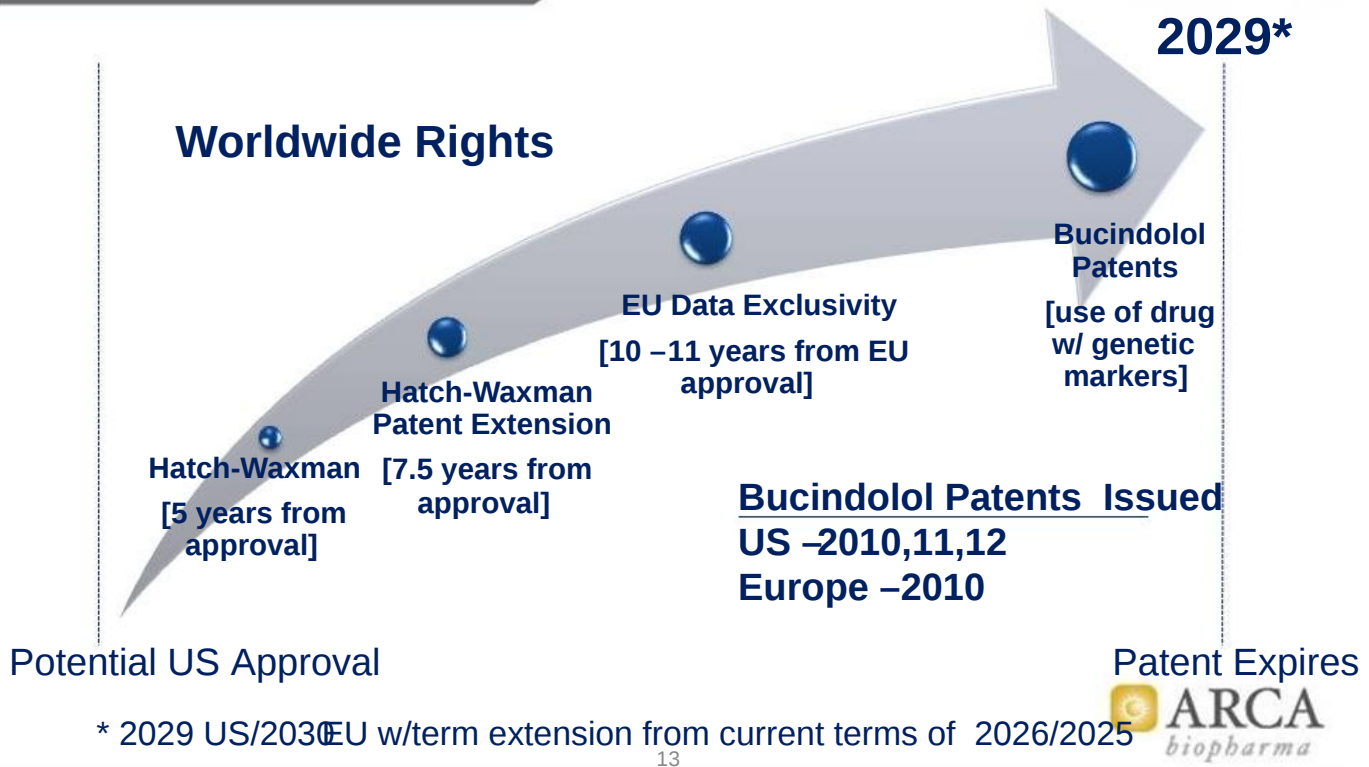
# Atrial Fibrillation

- Regulatory Strategy -

Obtain an atrial fibrillation approval in a genotype specific heart failure population via adaptive design Phase 2b/3 trial of 200/620 patients

- Clearly defined Regulatory Pathway
  - Similar endpoints used for most recent AF FDA approvals
  - Safety profile well characterized based on BEST & prior development
  - Company has understanding of pathway, safety profile and trial design
- Possibility of approval, based on GENETIC-AF (Phase3) if  $p \leq 0.01$ , when submitted with BEST trial data
- Second trial will likely be required if GENETIC-AF  $p > 0.01$

# Bucindolol Market Exclusivity / Intellectual Property Protection



# Capital Structure

(as of December 31, 2012)

- Shares outstanding: 2.66 million
- Dilutive securities outstanding: 1.68 million
  - Stock issued post 12/31/12: 521K
  - Warrants outstanding: 930K (at \$9.10 on weighted average)
  - Options outstanding: 144K (at \$18.29 on weighted average)
  - Shares under Equity Plan: 80K
- Current stock price (4/10/13): \$2.20 /share
- Current market capitalization: \$7.01 million
- Net cash: \$2.92 million



# Summary

- AF is an epidemic CV disease afflicting ~2.7 million patients & growing;
- Significant unmet need for treatment/prevention of AF, particularly in HFREF patients, and for rate control in HFREF (no other approved drugs for HFREF patients)
- Prior clinical data have indicated Gencaro to be safe and has shown potential treatment benefits in AF, both in the entire patient cohort, and especially in the "very favorable" genotype (~50% of patient population)
- Management team with extensive experience in CV disease, drug development and corporate execution
- Potential to be only beta-blocker indicated for AF prevention
- Potential to be the first genetically-targeted AF treatment