Edgar Filing: ARCA biopharma, Inc. - Form 424B4

ARCA biopharma, Inc. Form 424B4 July 25, 2013 Prospects Supplement No. 3

Filed pursuant to Rule 424 (b)(4)

(to Prospectus dated May 30, 2013)

Registration No. 333-187508

125,000 Shares of Series A Convertible Preferred Stock

12,500,000 Shares of Common Stock Underlying the Preferred Stock

Warrants to Purchase up to 6,250,000 Shares of Common Stock and

6,250,000 Shares of Common Stock Underlying the Warrants

#### ARCA biopharma, Inc.

This prospectus supplement supplements the prospectus dated May 30, 2013 (the Prospectus ), as supplemented by that certain Prospectus Supplement No. 1 dated July 17, 2013 (Supplement No. 1), and by that certain Prospectus Supplement No. 2 dated July 19, 2013 (Supplement No. 2), which forms a part of our Registration Statement on Form S-1 (Registration No. 333-187508). This prospectus supplement is being filed to update and supplement the information in the Prospectus, Supplement No. 1 and Supplement No. 2 with the information contained in our current report on Form 8-K, filed with the Securities and Exchange Commission (the Commission) on July 24, 2013 (the Current Report). Accordingly, we have attached the Current Report to this prospectus supplement.

The Prospectus, Supplement No. 1, Supplement No. 2 and this prospectus supplement relate to the offer and sale of up to 125,000 shares of Series A Convertible Preferred Stock ( Preferred Stock ) which are convertible into 12,500,000 shares of Common Stock, warrants to purchase up to 6,250,000 shares of our Common Stock and 6,250,000 shares of Common Stock underlying the warrants.

This prospectus supplement should be read in conjunction with the Prospectus, Supplement No. 1 and Supplement No. 2. This prospectus supplement updates and supplements the information in the Prospectus, Supplement No. 1 and Supplement No. 2. If there is any inconsistency between the information in the Prospectus, Supplement No. 1, Supplement No. 2 and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our common stock is traded on the Nasdaq Global Market under the trading symbol ABIO. On July 24, 2013, the last reported sale price of our common stock was \$1.44 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 5 of the Prospectus and beginning on page 23 of our quarterly report on Form 10-Q for the quarterly period ended March 31, 2013 before you decide whether to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is July 24, 2013

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

# FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 24, 2013 (July 22, 2013)

# ARCA biopharma, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction 000-22873 (Commission 36-3855489 (I.R.S. Employer

of Incorporation)

File Number) 8001 Arista Place, Suite 430, Broomfield, CO 80021 **Identification No.)** 

## Edgar Filing: ARCA biopharma, Inc. - Form 424B4

(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)

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))

#### Section 8 Other Events

#### Item 8.01. Other Events.

On July 22, 2013, ARCA biopharma, Inc. ( ARCA ) announced that it has expanded the clinical trial leadership team with three new hires in clinical development and quality assurance. The press release is furnished as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

Additionally, on July 24, 2013, ARCA announced the Steering Committee for GENETIC-AF, ARCA s Phase 2B/3 trial evaluating Gencaro as a potential treatment for atrial fibrillation. The Steering Committee is comprised of experts in the field of cardiology and electrophysiology, particularly in clinical development. The press release is furnished as Exhibit 99.2 hereto, the contents of which are incorporated herein by reference.

#### Section 9 Financial Statements and Exhibits

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release titled ARCA biopharma Announces Additions to GENETIC-AF Leadership Team; Team Will Oversee Execution of GENETIC-AF Clinical Trial Evaluating Gencaro as Potential Treatment for Atrial Fibrillation dated July 22, 2013.
99.2	Press Release titled ARCA biopharma Announces Steering Committee for GENETIC-AF Trial; Cardiology and Electrophysiology Experts to Provide Scientific Oversight and Guidance for Phase 2B/3 Clinical Trial of Gencaro as a Potential Treatment for Atrial Fibrillation dated July 24, 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: July 24, 2013

ARCA biopharma, Inc.

(Registrant)

By: /s/ Patrick M. Wheeler Name: Patrick M. Wheeler Title: Chief Financial Officer

# INDEX TO EXHIBITS

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99.2	Press Release titled ARCA biopharma Announces Steering Committee for GENETIC-AF Trial; Cardiology and Electrophysiology Experts to Provide Scientific Oversight and Guidance for Phase 2B/3 Clinical Trial of Gencaro as a Potential Treatment for Atrial Fibrillation dated July 24, 2013.

Exhibit 99.1

#### ARCA biopharma Announces Additions to GENETIC-AF Leadership Team

#### Team Will Oversee Execution of GENETIC-AF Clinical Trial Evaluating Gencaro as Potential Treatment for Atrial Fibrillation

*Broomfield, Colorado, July 22, 2013* ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced that it has expanded the Company s clinical trial leadership team with three new hires in clinical development and quality assurance: vice president clinical development, senior director quality, and senior clinical program manager.

These new hires will join existing ARCA employees in overseeing the execution of GENETIC-AF, the Company s Phase 2B/3 clinical trial evaluating Gencaro as a potential treatment for atrial fibrillation.

We are very pleased to have these industry professionals, who collectively have over 45 years of clinical development and QA experience, join ARCA as key members of our team, said Dr. Michael R. Bristow, President and CEO. Their understanding of the drug development process and clinical trial execution will be a tremendous asset as ARCA continues the development of Gencaro as a potential treatment for atrial fibrillation.

Christopher Dufton, PhD, Vice President, Clinical Development, was previously Director of Clinical Research at Gilead Sciences. Prior to Gilead, Dr. Dufton was Associate Director of Clinical Development at Myogen, Inc., where he was a member of the development team responsible for the clinical program that led to the approval of Letairis® (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH). Letairis is now approved in the U.S. and Europe for the treatment of PAH.

Sharon Perry, Senior Director Quality, was previously Director of Quality Assurance (QA) at Accera Pharma. Ms. Perry also brings additional relevant QA experience from her prior work at Gilead Sciences, PR Pharmaceuticals and Pfizer.

Jennifer Merriweather, Senior Clinical Program Manager was previously Clinical Program Manager at Gilead Sciences. Ms. Merriweather also brings additional relevant clinical development experience from her work with Myogen, Inc.

#### About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company s lead product candidate, Gencaro<sup>TM</sup> (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for

atrial fibrillation. 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 atrial fibrillation prevention treatment. ARCA has partnered with Medtronic, Inc. for the Phase 2B portion of the GENETIC-AF trial. For more information please visit <a href="https://www.arcabiopharma.com">www.arcabiopharma.com</a>.

#### 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 execution of the upcoming GENETIC-AF trial, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro s potential to treat atrial fibrillation, future treatment options for patients with atrial fibrillation, and the potential for Gencaro to be the first genetically-targeted atrial fibrillation 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: the Company s financial resources and whether they will be sufficient to meet the Company s business objectives and operational requirements; results of earlier clinical trials may not be confirmed in future trials, the protection and market exclusivity provided by the Company 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 SEC, including without limitation the Company s annual report on Form 10-K for the year ended December 31, 2012, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

#### **Contact:**

Derek Cole

Investor Relations Advisory Solutions

720.940.2163, derek.cole@arcabiopharma.com

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Exhibit 99.2

### ARCA BIOPHARMA ANNOUNCES STEERING COMMITTEE FOR

#### **GENETIC-AF TRIAL**

#### Cardiology and Electrophysiology Experts to Provide Scientific Oversight and Guidance

#### for Phase 2B/3 Clinical Trial of Gencaro as a Potential Treatment for Atrial Fibrillation

*Broomfield, CO, July 24, 2013* ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced the Steering Committee for GENETIC-AF, the Company s Phase 2B/3 trial evaluating GencaroTM (bucindolol hydrochloride) as a potential treatment for atrial fibrillation. The Steering Committee is comprised of experts in the field of cardiology and electrophysiology, particularly in clinical development.

Stuart Connolly, MD, Director of the Division of Cardiology at McMaster University in Hamilton, Ontario, has been appointed Chairman of the Steering Committee. William T. Abraham, MD, Director of the Division of Cardiovascular Medicine at The Ohio State University Wexner Medical Center, has been appointed co-Chair of the Steering Committee.

The Steering Committee of GENETIC-AF provides a balance of atrial fibrillation and heart failure clinical trials expertise, with each member being an expert in one or the other or both, said Dr. Michael R. Bristow, President and Chief Executive Officer of ARCA. We are delighted to have Dr. Connolly chair the Steering Committee. He brings a wealth of experience over a distinguished career in the field of electrophysiology, particularly in clinical trials in atrial fibrillation, which makes him a natural fit to help guide the development of Gencaro. Dr. Abraham is also an expert in heart failure clinical investigation and brings a background of leadership in both drug and device trials in chronic heart failure populations. Thus, GENETIC-AF will have the benefit of trial leadership that is at the forefront of both atrial fibrillation and heart failure outcome trials.

I am honored to participate in the GENETIC-AF trial, an innovative approach to evaluating the potential efficacy of Gencaro as a treatment for atrial fibrillation, said Dr. Connolly. Atrial fibrillation is a growing problem where current medical therapy does not provide adequate treatment, particularly in heart failure populations. I look forward to working with the teams at ARCA and Medtronic to advance a potential new treatment for patients at high risk for developing, or living with, atrial fibrillation.

Dr. Abraham said, I am pleased to be closely involved with the GENETIC-AF trial, which explores new territory on two important fronts: prospective identification of a genetic subpopulation potentially more responsive to a cardiovascular drug, and demonstration that a drug, in this case Gencaro, may be safe and effective in preventing atrial fibrillation in the unmet need population of heart failure with reduced left ventricular ejection fraction.

Additional Steering Committee members are:

Inder Anand, MD, of the University of Minnesota and Director of the Heart Failure Program at the Minneapolis VA Medical Center;

David E. Haines, MD, Director of the Heart Rhythm Center of William Beaumont Hospital;

Jonathan P. Piccini, MD, Director, Cardiac Electrophysiology Clinical Trials Program, Duke University Medical Center;

William H. Sauer MD, Director of the Electrophysiology Program at the University of Colorado Denver; and,

Dirk J. van Veldhuisen, MD, Chairman of Cardiology at the University Medical Center Groningen, the Netherlands. The Steering Committee will provide scientific oversight for the GENETIC-AF trial as well as communicate its recommendations regarding trial conduct with the trial s Data Safety Monitoring Board.

#### **GENETIC-AF Clinical Trial**

GENETIC-AF is planned as a Phase 2B/3, multi-center, randomized, double-blind clinical trial comparing Gencaro to metoprolol CR/XL for prevention of AF in patients with heart failure and reduced left ventricular ejection fraction (HFREF). ARCA plans to enroll only patients with the genetic variant of the beta-1 cardiac receptor which the Company believes responds most favorably to Gencaro. GENETIC-AF has an adaptive design, under which the Company plans to initiate it as a Phase 2B study in approximately 200 patients and then, depending on the results of an interim analysis by the trial Data Safety Monitoring Board (DSMB), expand the trial to a Phase 3 study by enrolling an estimated additional 420 patients. The Company anticipates that patient enrollment in GENETIC-AF will begin in the first quarter of 2014.

#### About ARCA biopharma

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#### Safe Harbor Statement

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