ARCA biopharma, Inc.
Form 424B4
December 05, 2013

Prospects Supplement No. 12 **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), by that certain Prospectus Supplement No. 2 dated July 19, 2013 (Supplement No. 2), by that certain Prospectus Supplement No. 3 dated July 24, 2013 (Supplement No. 3), by that certain Prospectus Supplement No. 4 dated July 30, 2013 (Supplement No. 4), by that certain Prospectus Supplement No. 5 dated August 6, 2013 (Supplement No. 5), by that certain Prospectus Supplement No. 6 dated September 4, 2013 (Supplement No. 6), by that certain Prospectus Supplement No. 7 dated September 23, 2013 (Supplement No. 7), by that certain Prospectus Supplement No. 8 dated October 29, 2013 (Supplement No. 8), by that certain Prospectus Supplement No. 9 dated November 6, 2013 (Supplement No. 9), by that certain Prospectus Supplement No. 10 dated November 13, 2013 (Supplement No. 10), and by that certain Prospectus Supplement No. 11 dated November 21, 2013 (Supplement No. 11 , and together with Supplement No. 1, Supplement No. 2, Supplement No. 3, Supplement No. 4, Supplement No. 5, Supplement No. 6, Supplement No. 7, Supplement No. 8, Supplement No. 9, and Supplement No. 10, the Supplements), which form 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 and the Supplements with the information contained in our current report on Form 8-K, filed with the Securities and Exchange Commission (the Commission) on December 5, 2013 (the Current Report). Accordingly, we have attached the Current Report to this prospectus supplement.

The Prospectus, the Supplements 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 and the Supplements. This prospectus supplement updates and supplements the information in the Prospectus and the Supplements. If there is any inconsistency between the information in the Prospectus, the Supplements 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 December 5, 2013, the last reported sale price of our common stock was $1.65 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 September 30, 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 December 5, 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): December 5, 2013 (December 4, 2013)

ARCA biopharma, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	000-22873	36-3855489
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

11080 CirclePoint Road, Suite 140, Westminster, CO 80020

(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 December 4, 2013, ARCA biopharma, Inc. (ARCA) announced that its Investigational New Drug application for Gencaro™, a pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation, has been accepted by the U.S. Food and Drug Administration and is now active. The press release is furnished as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

Additionally, on December 5, 2013, ARCA announced that Laboratory Corporation of America (LabCorp®) has submitted an Investigational Device Exemption application to the U.S. Food and Drug Administration for the planned companion diagnostic test for Gencaro. 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 U.S. FDA Acceptance of Gencaro IND Application for the Treatment of Atrial Fibrillation dated December 4, 2013.
99.2	Press Release titled ARCA biopharma Announces IDE Submission to U.S. FDA for Gencaro Companion Diagnostic Test dated December 5, 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: December 5, 2013

ARCA biopharma, Inc.

(Registrant)

By: /s/ Christopher D. Ozeroff
Name: Christopher D. Ozeroff

Title: SVP and General Counsel

INDEX TO EXHIBITS

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Exhibit 99.1

ARCA BIOPHARMA ANNOUNCES US FDA ACCEPTANCE OF GENCARO IND

APPLICATION FOR THE TREATMENT OF ATRIAL FIBRILLATION

Phase 2B/3 GENETIC-AF Trial on Track to Begin Patient Enrollment in Q1 2014

Gencaro Potentially the First Genetically-Targeted Cardiovascular Treatment

Westminster, CO, December 4, 2013 ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced that the Company s Gencaro™ Investigational New Drug (IND) application for atrial fibrillation (AF) has been accepted by the U.S. Food and Drug Administration (FDA) and is now active.

ARCA plans to evaluate Gencaro, a pharmacologically unique beta-blocker and mild vasodilator, as a potential treatment for atrial fibrillation in the Phase 2B/3 GENETIC-AF clinical trial, which is expected to begin enrolling patients in the first quarter of 2014. ARCA has identified common genetic variations that it believes predict individual patient response to Gencaro, giving it potential to be the first genetically-targeted therapy for the prevention of atrial fibrillation.

Dr. Michael R. Bristow, Founder and CEO of ARCA, and a pioneer of beta-blockade development commented, At ARCA, we believe a personalized medicine approach to drug development, tailoring medical treatment to the individual genetic characteristics of each patient, can enable more effective therapies, improve patient outcomes and reduce healthcare costs. If the GENETIC-AF trial successfully confirms the atrial fibrillation data analysis from a prior Phase 3 clinical trial, Gencaro has the potential to be the first genetically targeted treatment for the prevention of this important cardiovascular disorder and provide a much needed treatment option for patients in an area of high unmet medical need.

GENETIC-AF Clinical Trial

GENETIC-AF is planned as a Phase 2B/3, multi-center, randomized, double-blind clinical trial comparing Gencaro to Toprol-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

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company s lead product candidate, Gencaro™ (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 a collaboration with Medtronic, Inc. for support of the GENETIC-AF trial. For more information please visit www.arcabiopharma.com.

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, potential timing for patient enrollment in the GENETIC-AF trial, the sufficiency of the Company s capital to support its operations, 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, the role of AF burden in diagnosis and treatment of 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.

Investor & Media Contact:

Derek Cole

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Exhibit 99.2

ARCA BIOPHARMA ANNOUNCES IDE SUBMISSION TO US FDA FOR GENCARO

COMPANION DIAGNOSTIC TEST

Phase 2B/3 GENETIC-AF Trial on Track to Begin Patient Enrollment in Q1 2014

Westminster, CO, December 5, 2013 ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced that Laboratory Corporation of America (LabCorp®) (NYSE: LH) has informed ARCA that LabCorp has submitted an Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration (FDA) for the planned companion diagnostic test for Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation (AF). If accepted by the FDA, the IDE will allow the companion diagnostic test to be used in the planned GENETIC-AF clinical trial. ARCA s Gencaro Investigational New Drug (IND) application for AF has been accepted by the U.S. Food and Drug Administration (FDA) and is active.

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. LabCorp and ARCA have developed the companion diagnostic test for Gencaro to identify patient genotypes based on these genetic variations of the beta-1 cardiac receptor. LabCorp will provide the patient genetic testing for ARCA s GENETIC-AF clinical trial of Gencaro, which is expected to begin patient enrollment in the first quarter of 2014.

GENETIC-AF Clinical Trial

GENETIC-AF is planned as a Phase 2B/3, multi-center, randomized, double-blind clinical trial comparing Gencaro to Toprol-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.

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