ARCA biopharma, Inc.
Form 424B4
November 06, 2013

Prospects Supplement No. 9 **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), and by that certain Prospectus Supplement No. 8 dated October 29, 2013 (Supplement No. 8 and together with Supplement No. 1, Supplement No. 2, Supplement No. 3, Supplement No. 4, Supplement No. 5, Supplement No. 6, and Supplement No. 7, 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 November 6, 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 November 6, 2013, the last reported sale price of our common stock was $1.40 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 22 of our quarterly report on Form 10-Q for the quarterly period ended June 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 November 6, 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): November 6, 2013 (November 5, 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))

Item 1.01 Entry into a Material Definitive Agreement

On November 5, 2013, ARCA biopharma, Inc. (ARCA) entered into a Clinical Research Agreement (the Agreement) with Duke University s Duke Clinical Research Institute (DCRI), to serve as the coordinating center and principal investigator for GENETIC-AF (the Study), a planned Phase 2B/3 genetically-targeted, comparative effectiveness clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a potential treatment for the prevention of atrial fibrillation in patients with heart failure.

Under the Agreement, the DCRI will coordinate GENETIC-AF with the approximately 50 clinical sites in the United States that are planned to participate in the Study (the Study Sites) and the physician investigators at the Study Sites. The DCRI will enter into an agreement with each Study Site, and will provide all materials needed by the Study Sites to conduct the Study, including Gencaro and the comparator drug. All data generated from GENETIC-AF will be owned by ARCA, with the DCRI retaining the right to use the data for its internal, non-commercial purposes. All inventions directly related to Gencaro or arising from the protocol of the Study will be owned by ARCA, with ARCA having the option to license any other inventions arising from the Study. The publication of any peer-reviewed manuscripts will be reviewed and be subject to approval by a publications committee, which will be overseen by the steering committee of GENETIC-AF. The DCRI s obligation to conduct GENETIC-AF is subject to the approval of the DCRI Institutional Review Board.

The term of the Agreement will continue for the duration of the Study. ARCA may terminate the Agreement upon 90 days notice for any reason. In addition, the Agreement may be terminated immediately if the FDA withdraws approval for the Study, if animal, human or toxicological test results support termination of the Study, if adverse events related to the drugs administered in the Study emerge that support immediate termination, if the principal investigator at the DCRI cannot continue in that role and a successor acceptable to ARCA is not available, or if a material event occurs that affects ARCA s ability to finance the Study.

The foregoing summary is qualified in its entirety by reference to the Agreement, a copy of which will be filed with the Company s Annual Report on Form 10-K. Certain portions of the Agreement will be omitted and will be subject to a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The omitted material will be included in the request for confidential treatment.

A press release announcing the Agreement is also attached as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled ARCA biopharma Announces Clinical Trial Agreement for GENETIC-AF Trial, dated November 6, 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: November 6, 2013

ARCA biopharma, Inc.

(Registrant)

By: /s/ Christopher D. Ozeroff
Name: Christopher D. Ozeroff
Title: Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release titled ARCA biopharma Announces Clinical Trial Agreement for GENETIC-AF Trial, dated November 6, 2013.

Exhibit 99.1

ARCA BIOPHARMA ANNOUNCES CLINICAL TRIAL AGREEMENT FOR

GENETIC-AF TRIAL

Gencaro Potentially the First Genetically-Targeted AF Prevention Treatment

Westminster, CO, November 6, 2013 ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, and Duke University s Duke Clinical Research Institute (DCRI), the world s largest academic clinical research organization (ARO), today announced a new agreement under which ARCA and the DCRI will work together to execute GENETIC-AF, a planned Phase 2B/3 genetically-targeted, comparative effectiveness clinical trial evaluating Gencaro (bucindolol hydrochloride) as a potential treatment for the prevention of atrial fibrillation (AF) in patients with heart failure. Patient enrollment in GENETIC-AF is expected to begin in the first quarter of 2014.

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 therapy for the prevention of AF.

The DCRI will serve as the coordinating center and principal investigator for GENETIC-AF. The DCRI has substantial experience in conducting multicenter trials in atrial fibrillation, having been the ARO for several large recently completed AF trials, which had a combined enrollment of more than 32,000 AF patients.

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/or 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 a Phase 2B trial in approximately 200 patients and then, depending on the results of an interim analysis by the trial Data Safety Monitoring Board (DSMB), transition the trial to a Phase 3 trial with the enrollment of approximately 420 additional 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 therapy for the prevention of atrial fibrillation. ARCA has a collaboration with Medtronic, Inc. for support of the GENETIC-AF trial. For more information please visit www.arcabiopharma.com.

About Duke Clinical Research Institute (DCRI)

The Duke Clinical Research Institute, a department of Duke University, is the world s largest academic clinical research organization and is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research. The DCRI has worked with more than 14,000 investigators at nearly 37,000 sites in 65 countries. The DCRI has conducted more than 970 Phase I IV studies and outcomes research projects with a combined enrollment of more than 1.2 million patients. The DCRI s legacy of research has generated more than 8,300 publications in peer-reviewed journals.

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 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 significance of the DCRI s experience in clinical trial management on the execution and outcome of GENETIC-AF 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.

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